

Table 14.4-2

Statistical Comparison Between Smokers and Non-Smokers by Gender of 24-Hour Urine Biomarkers of Exposure by Timepoint and Overall

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Nicotine (ug/24hr)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	2338.360, 1614.220	2416.280, 1539.710	2388.230, 1566.130	8.489, 2.808	2.314, 1.980	5.121, 2.321
	SD, SE	1411.7400, 332.7500	1963.9900, 347.1880	1770.0800, 250.3270	19.1396, 3.4944	1.4995, 0.2499	13.2003, 1.6248
	MEDIAN	2319.820	1879.750	2032.230	2.018	1.965	1.980
	MIN, MAX	22.137, 4893.750	116.325, 6337.875	22.137, 6337.875	0.530, 88.160	0.570, 7.776	0.530, 88.160
	5%, 95%	22.137, 4893.750	152.361, 6081.580	152.361, 5830.270	0.650, 63.054	0.800, 6.825	0.800, 17.248
	BLQ Values Included	0	0	0	15	29	44
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	2363.200, 1645.410	2590.040, 1722.630	2506.710, 1693.850	14.592, 2.585	2.407, 2.079	7.945, 2.295
	SD, SE	1282.6200, 302.3160	2121.2400, 380.9860	1845.8400, 263.6920	63.1483, 11.5293	1.4070, 0.2345	42.6331, 5.2478
	MEDIAN	2157.760	2081.690	2099.050	1.680	2.180	2.088
	MIN, MAX	10.710, 4608.540	150.672, 9552.459	10.710, 9552.459	0.625, 348.555	0.660, 7.128	0.625, 348.555
	5%, 95%	10.710, 4608.540	192.780, 5988.020	192.780, 5810.680	0.815, 14.926	0.750, 6.160	0.815, 7.128
	BLQ Values Included	0	0	0	19	32	51
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	2835.840, 1478.690	2679.760, 2063.140	2737.440, 1824.200	3.438, 2.468	2.207, 2.052	2.766, 2.232
	SD, SE	2590.2600, 628.2300	1574.9800, 292.4670	1983.6400, 292.4720	3.7708, 0.6885	0.8545, 0.1424	2.6681, 0.3284
	MEDIAN	1851.270	2397.850	2327.150	2.125	2.050	2.082
	MIN, MAX	10.061, 7734.320	95.232, 5749.170	10.061, 7734.320	0.750, 19.760	0.940, 4.740	0.750, 19.760
	5%, 95%	10.061, 7734.320	420.000, 5508.020	288.769, 7314.620	0.750, 8.410	0.990, 3.948	0.990, 7.224
	BLQ Values Included	0	0	0	19	33	52
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	2520.490, 1688.990	2484.740, 1756.540	2497.610, 1731.920	8.840, 3.003	2.309, 2.097	5.278, 2.469
	SD, SE	1535.5400, 361.9290	1748.8000, 309.1460	1659.2700, 234.6560	25.2248, 4.6054	1.0377, 0.1729	17.1813, 2.1149
	MEDIAN	2405.250	1934.390	2046.090	1.953	2.180	2.147
	MIN, MAX	14.303, 5334.180	162.499, 6909.320	14.303, 6909.320	0.977, 138.186	0.967, 4.729	0.967, 138.186
	5%, 95%	14.303, 5334.180	172.571, 5294.820	172.571, 5294.820	1.057, 32.968	0.980, 4.724	1.057, 11.448

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Nicotine (nmol/24hr)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	14416.000, 9951.700	14896.400, 9492.290	14723.500, 9655.180	52.337, 17.310	14.269, 12.205	31.572, 14.306
	SD, SE	8703.3800, 2051.4100	12108.0000, 2140.4100	10912.6000, 1543.2700	117.9960, 21.5430	9.2444, 1.5407	81.3796, 10.0171
	MEDIAN	14301.700	11588.600	12528.700	12.438	12.115	12.207
	MIN, MAX	136.475, 30169.969	717.144, 39072.999	136.475, 39072.999	3.267, 543.506	3.514, 47.939	3.267, 543.506
	5%, 95%	136.475, 30170.000	939.306, 37492.900	939.306, 35943.600	4.007, 388.728	4.932, 42.076	4.932, 106.334
	BLQ Values Included	0	0	0	15	29	44
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	14569.100, 10144.000	15967.600, 10620.000	15453.900, 10442.600	89.959, 15.936	14.838, 12.818	48.983, 14.152
	SD, SE	7907.3400, 1863.7800	13077.4000, 2348.7800	11379.6000, 1625.6600	389.3100, 71.0779	8.6742, 1.4457	262.8330, 32.3525
	MEDIAN	13302.600	12833.600	12940.600	10.357	13.440	12.870
	MIN, MAX	66.027, 28411.649	928.893, 58890.910	66.027, 58890.910	3.853, 2148.842	4.069, 43.944	3.853, 2148.842
	5%, 95%	66.027, 28411.600	1188.490, 36916.100	1188.490, 35822.800	5.024, 92.019	4.624, 37.976	5.024, 43.944
	BLQ Values Included	0	0	0	19	32	51
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	17482.900, 9116.140	16520.700, 12719.300	16876.300, 11246.200	21.194, 15.216	13.605, 12.649	17.055, 13.757
	SD, SE	15968.9000, 3873.0400	9709.7600, 1803.0600	12229.2000, 1803.0900	23.2470, 4.2443	5.2682, 0.8780	16.4485, 2.0247
	MEDIAN	11413.100	14782.700	14346.900	13.101	12.638	12.836
	MIN, MAX	62.026, 47682.083	587.105, 35443.633	62.026, 47682.083	4.624, 121.820	5.795, 29.222	4.624, 121.820
	5%, 95%	62.026, 47682.100	2589.300, 33957.000	1780.260, 45094.600	4.624, 51.848	6.103, 24.339	6.103, 44.536
	BLQ Values Included	0	0	0	19	33	52
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	15538.800, 10412.600	15318.400, 10829.100	15397.800, 10677.300	54.496, 18.515	14.237, 12.925	32.537, 15.219
	SD, SE	9466.5800, 2231.2900	10781.3000, 1905.8900	10229.4000, 1446.6500	155.5110, 28.3923	6.3971, 1.0662	105.9230, 13.0382
	MEDIAN	14828.400	11925.500	12614.200	12.042	13.440	13.235
	MIN, MAX	88.176, 32885.200	1001.810, 42596.000	88.176, 42596.000	6.021, 851.919	5.960, 29.152	5.960, 851.919
	5%, 95%	88.176, 32885.200	1063.900, 32642.600	1063.900, 32642.600	6.514, 203.248	6.042, 29.125	6.514, 70.579

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., <1.234 will be used as 1.234) for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Nicotine (ug/mg Creatinin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1.996, 1.221	2.034, 1.343	2.020, 1.298	0.005, NA	0.002, NA	0.003, NA
	SD, SE	2.0759, 0.4893	1.5540, 0.2747	1.7387, 0.2459	0.0109, 0.0020	0.0018, 0.0003	0.0075, 0.0009
	MEDIAN	1.526	1.792	1.727	0.001	0.002	0.002
	MIN, MAX	0.021, 9.353	0.097, 5.798	0.021, 9.353	0.000, 0.044	0.000, 0.011	0.000, 0.044
	5%, 95%	0.021, 9.353	0.100, 5.254	0.100, 5.254	0.000, 0.042	0.001, 0.005	0.000, 0.011
	BLQ Values Included	0	0	0	15	29	44
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	1.880, 1.210	2.029, 1.368	1.974, 1.307	0.013, NA	0.002, NA	0.007, NA
	SD, SE	1.6531, 0.3896	1.7171, 0.3084	1.6781, 0.2397	0.0605, 0.0110	0.0014, 0.0002	0.0408, 0.0050
	MEDIAN	1.681	1.752	1.686	0.001	0.002	0.002
	MIN, MAX	0.012, 7.451	0.130, 7.495	0.012, 7.495	0.000, 0.333	0.000, 0.007	0.000, 0.333
	5%, 95%	0.012, 7.451	0.144, 6.431	0.144, 6.431	0.000, 0.017	0.001, 0.004	0.000, 0.004
	BLQ Values Included	0	0	0	19	32	51
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	1.814, 1.068	2.267, 1.760	2.100, 1.463	0.002, NA	0.002, 0.002	0.002, NA
	SD, SE	1.3903, 0.3372	1.3884, 0.2578	1.3912, 0.2051	0.0021, 0.0004	0.0012, 0.0002	0.0017, 0.0002
	MEDIAN	1.555	2.175	2.056	0.001	0.002	0.002
	MIN, MAX	0.009, 4.966	0.095, 5.794	0.009, 5.794	0.000, 0.011	0.001, 0.005	0.000, 0.011
	5%, 95%	0.009, 4.966	0.494, 5.392	0.200, 4.966	0.000, 0.005	0.001, 0.005	0.000, 0.005
	BLQ Values Included	0	0	0	19	33	52
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1.899, 1.237	2.099, 1.497	2.027, 1.398	0.007, NA	0.002, NA	0.004, NA
	SD, SE	1.4598, 0.3441	1.4870, 0.2629	1.4655, 0.2073	0.0228, 0.0042	0.0012, 0.0002	0.0154, 0.0019
	MEDIAN	1.741	1.849	1.811	0.001	0.002	0.002
	MIN, MAX	0.014, 6.341	0.122, 5.778	0.014, 6.341	0.000, 0.126	0.000, 0.006	0.000, 0.126
	5%, 95%	0.014, 6.341	0.156, 5.620	0.156, 5.620	0.000, 0.015	0.001, 0.004	0.000, 0.008

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
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OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Nicotine (nmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	12.307, 7.529	12.540, 8.279	12.456, 8.001	0.031, NA	0.013, NA	0.021, NA
	SD, SE	12.7977, 3.0165	9.5803, 1.6936	10.7192, 1.5159	0.0670, 0.0122	0.0109, 0.0018	0.0463, 0.0057
	MEDIAN	9.408	11.045	10.644	0.006	0.012	0.012
	MIN, MAX	0.129, 57.661	0.598, 35.745	0.129, 57.661	0.000, 0.271	0.000, 0.068	0.000, 0.271
	5%, 95%	0.129, 57.661	0.617, 32.391	0.617, 32.391	0.000, 0.259	0.006, 0.031	0.000, 0.068
	BLQ Values Included	0	0	0	15	29	44
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	11.587, 7.457	12.509, 8.432	12.170, 8.060	0.081, NA	0.013, NA	0.044, NA
	SD, SE	10.1915, 2.4022	10.5861, 1.9013	10.3455, 1.4779	0.3729, 0.0681	0.0087, 0.0015	0.2515, 0.0310
	MEDIAN	10.361	10.801	10.394	0.006	0.012	0.009
	MIN, MAX	0.074, 45.935	0.801, 46.207	0.074, 46.207	0.000, 2.053	0.000, 0.043	0.000, 2.053
	5%, 95%	0.074, 45.935	0.888, 39.647	0.888, 39.647	0.000, 0.105	0.006, 0.025	0.000, 0.025
	BLQ Values Included	0	0	0	19	32	51
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	11.184, 6.582	13.978, 10.849	12.945, 9.019	0.011, NA	0.013, 0.011	0.012, NA
	SD, SE	8.5709, 2.0788	8.5594, 1.5894	8.5770, 1.2646	0.0130, 0.0024	0.0073, 0.0012	0.0102, 0.0013
	MEDIAN	9.587	13.409	12.673	0.006	0.012	0.012
	MIN, MAX	0.055, 30.615	0.586, 35.720	0.055, 35.720	0.000, 0.068	0.006, 0.031	0.000, 0.068
	5%, 95%	0.055, 30.615	3.046, 33.242	1.233, 30.615	0.000, 0.031	0.006, 0.031	0.000, 0.031
	BLQ Values Included	0	0	0	19	33	52
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	11.710, 7.628	12.938, 9.229	12.496, 8.617	0.041, 0.011	0.013, 0.011	0.026, 0.011
	SD, SE	8.9997, 2.1212	9.1678, 1.6207	9.0349, 1.2777	0.1408, 0.0257	0.0073, 0.0012	0.0952, 0.0117
	MEDIAN	10.731	11.396	11.165	0.008	0.011	0.010
	MIN, MAX	0.086, 39.094	0.753, 35.623	0.086, 39.094	0.002, 0.779	0.002, 0.037	0.002, 0.779
	5%, 95%	0.086, 39.094	0.960, 34.649	0.960, 34.649	0.002, 0.094	0.006, 0.025	0.002, 0.049

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OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Nicotine (ug/24hr)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1685.190, 1137.840	1778.700, 1034.080	1745.040, 1070.290	7.867, 2.456	2.180, 1.880	4.765, 2.123
	SD, SE	1101.8200, 259.7020	1601.3000, 283.0720	1430.2000, 202.2600	19.3657, 3.5357	1.5252, 0.2542	13.2934, 1.6363
	MEDIAN	1444.190	1281.880	1417.230	1.619	1.875	1.825
	MIN, MAX	18.048, 3521.714	76.527, 5245.860	18.048, 5245.860	0.530, 93.100	0.570, 9.792	0.530, 93.100
	5%, 95%	18.048, 3521.710	83.814, 5088.650	83.814, 4727.380	0.780, 58.311	0.800, 3.350	0.800, 13.992
	BLQ Values Included	0	0	0	18	34	52
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	1746.580, 1234.840	1840.680, 1134.230	1806.110, 1170.200	12.592, 2.332	2.317, 2.021	6.987, 2.157
	SD, SE	992.7280, 233.9880	1545.7500, 277.6240	1358.1100, 194.0160	54.8383, 10.0121	1.3916, 0.2319	37.0042, 4.5549
	MEDIAN	1592.530	1490.080	1573.750	1.680	2.155	2.013
	MIN, MAX	10.980, 3494.785	81.312, 5904.527	10.980, 5904.527	0.625, 302.670	0.660, 8.514	0.625, 302.670
	5%, 95%	10.980, 3494.790	94.792, 4764.320	94.792, 4729.200	0.815, 12.512	0.750, 4.585	0.815, 6.758
	BLQ Values Included	0	0	0	22	33	55
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	2172.220, 1008.700	1952.180, 1443.640	2033.500, 1264.500	2.702, 2.114	2.139, 1.995	2.395, 2.049
	SD, SE	2176.7000, 527.9280	1234.0700, 229.1620	1625.9700, 239.7360	2.5477, 0.4651	0.8136, 0.1356	1.8255, 0.2247
	MEDIAN	1269.580	1954.260	1632.770	1.900	2.040	2.015
	MIN, MAX	5.450, 6614.080	55.800, 4262.175	5.450, 6614.080	0.750, 13.650	0.940, 4.740	0.750, 13.650
	5%, 95%	5.450, 6614.080	417.200, 4138.430	161.699, 5668.540	0.750, 7.259	0.990, 3.350	0.990, 4.740
	BLQ Values Included	0	0	0	23	35	58
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1878.760, 1253.990	1799.420, 1211.440	1827.980, 1226.590	7.721, 2.668	2.212, 2.021	4.716, 2.293
	SD, SE	1166.6200, 274.9750	1353.6800, 239.2990	1277.8800, 180.7190	22.2784, 4.0675	0.9755, 0.1626	15.1522, 1.8651
	MEDIAN	1786.220	1574.520	1696.910	1.863	2.150	2.147
	MIN, MAX	11.493, 3792.220	85.660, 4824.560	11.493, 4824.560	0.793, 121.310	0.967, 5.163	0.793, 121.310
	5%, 95%	11.493, 3792.220	130.092, 4300.000	130.092, 4297.930	0.865, 33.074	0.980, 4.270	0.980, 8.342

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Biomarker: Free Nicotine (nmol/24hr)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	10389.200, 7014.800	10965.700, 6375.080	10758.200, 6598.370	48.501, 15.139	13.440, 11.591	29.377, 13.087
	SD, SE	6792.7300, 1601.0600	9872.0000, 1745.1400	8817.1700, 1246.9400	119.3890, 21.7974	9.4029, 1.5672	81.9539, 10.0878
	MEDIAN	8903.460	7902.810	8737.190	9.978	11.560	11.251
	MIN, MAX	111.266, 21711.367	471.789, 32340.727	111.266, 32340.727	3.267, 573.962	3.514, 60.368	3.267, 573.962
	5%, 95%	111.266, 21711.400	516.713, 31371.500	516.713, 29144.300	4.809, 359.487	4.932, 20.653	4.932, 86.261
	BLQ Values Included	0	0	0	18	34	52
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	10767.600, 7612.790	11347.800, 6992.530	11134.700, 7214.280	77.631, 14.378	14.284, 12.458	43.078, 13.297
	SD, SE	6120.1700, 1442.5400	9529.5300, 1711.5500	8372.7600, 1196.1100	338.0780, 61.7243	8.5790, 1.4298	228.1310, 28.0810
	MEDIAN	9817.950	9186.320	9702.170	10.357	13.286	12.407
	MIN, MAX	67.692, 21545.350	501.288, 36401.409	67.692, 36401.409	3.853, 1865.961	4.069, 52.489	3.853, 1865.961
	5%, 95%	67.692, 21545.400	584.393, 29372.000	584.393, 29155.500	5.024, 77.136	4.624, 28.267	5.024, 41.663
	BLQ Values Included	0	0	0	22	33	55
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	13391.800, 6218.640	12035.200, 8900.040	12536.500, 7795.640	16.659, 13.035	13.185, 12.301	14.764, 12.630
	SD, SE	13419.4000, 3254.6800	7608.0600, 1412.7800	10024.1000, 1477.9700	15.7067, 2.8676	5.0159, 0.8360	11.2539, 1.3853
	MEDIAN	7826.960	12048.000	10066.000	11.714	12.577	12.423
	MIN, MAX	33.599, 40775.803	344.007, 26276.309	33.599, 40775.803	4.624, 84.152	5.795, 29.222	4.624, 84.152
	5%, 95%	33.599, 40775.800	2572.040, 25513.400	996.874, 34946.500	4.624, 44.752	6.103, 20.653	6.103, 29.222
	BLQ Values Included	0	0	0	23	35	58
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	11582.500, 7730.810	11093.400, 7468.500	11269.500, 7561.890	47.597, 16.446	13.636, 12.462	29.073, 14.137
	SD, SE	7192.2100, 1695.2200	8345.4400, 1475.2800	7878.1100, 1114.1300	137.3460, 25.0759	6.0138, 1.0023	93.4135, 11.4984
	MEDIAN	11012.100	9706.920	10461.500	11.484	13.255	13.235
	MIN, MAX	70.852, 23379.000	528.091, 29743.400	70.852, 29743.400	4.891, 747.878	5.960, 31.832	4.891, 747.878
	5%, 95%	70.852, 23379.000	802.015, 26509.500	802.015, 26496.800	5.331, 203.904	6.042, 26.323	6.042, 51.426

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Nicotine (ug/mg Creatinin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1.564, 0.861	1.543, 0.902	1.551, 0.887	0.005, NA	0.002, NA	0.003, NA
	SD, SE	1.9898, 0.4690	1.4185, 0.2508	1.6269, 0.2301	0.0106, 0.0019	0.0022, 0.0004	0.0074, 0.0009
	MEDIAN	1.038	1.072	1.072	0.001	0.002	0.002
	MIN, MAX	0.017, 8.892	0.030, 5.613	0.017, 8.892	0.000, 0.044	0.000, 0.014	0.000, 0.044
	5%, 95%	0.017, 8.892	0.071, 5.001	0.071, 5.001	0.000, 0.041	0.001, 0.003	0.000, 0.012
	BLQ Values Included	0	0	0	18	34	52
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	1.463, 0.906	1.458, 0.901	1.459, 0.903	0.011, NA	0.002, NA	0.006, NA
	SD, SE	1.5262, 0.3597	1.3118, 0.2356	1.3786, 0.1969	0.0525, 0.0096	0.0014, 0.0002	0.0354, 0.0044
	MEDIAN	1.135	1.262	1.262	0.001	0.002	0.001
	MIN, MAX	0.012, 6.916	0.064, 5.630	0.012, 6.916	0.000, 0.289	0.000, 0.008	0.000, 0.289
	5%, 95%	0.012, 6.916	0.071, 4.633	0.071, 4.633	0.000, 0.014	0.001, 0.004	0.000, 0.004
	BLQ Values Included	0	0	0	22	33	55
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	1.392, 0.730	1.667, 1.232	1.563, 1.015	0.001, NA	0.002, 0.002	0.002, NA
	SD, SE	1.1591, 0.2811	1.1687, 0.2170	1.1600, 0.1710	0.0015, 0.0003	0.0011, 0.0002	0.0013, 0.0002
	MEDIAN	1.218	1.493	1.471	0.001	0.002	0.002
	MIN, MAX	0.005, 4.246	0.056, 5.060	0.005, 5.060	0.000, 0.008	0.001, 0.005	0.000, 0.008
	5%, 95%	0.005, 4.246	0.357, 4.177	0.107, 4.177	0.000, 0.003	0.001, 0.005	0.000, 0.004
	BLQ Values Included	0	0	0	23	35	58
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1.477, 0.920	1.547, 1.032	1.522, 0.990	0.006, NA	0.002, NA	0.004, NA
	SD, SE	1.3164, 0.3103	1.2482, 0.2207	1.2602, 0.1782	0.0201, 0.0037	0.0013, 0.0002	0.0136, 0.0017
	MEDIAN	1.237	1.362	1.351	0.001	0.002	0.002
	MIN, MAX	0.011, 5.866	0.061, 5.434	0.011, 5.866	0.000, 0.111	0.000, 0.007	0.000, 0.111
	5%, 95%	0.011, 5.866	0.119, 4.066	0.119, 4.066	0.000, 0.015	0.001, 0.004	0.001, 0.006

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., <1.234) will be used as 1.234) for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Nicotine (nmol/mg Creatin)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	9.640, 5.307	9.514, 5.558	9.559, 5.466	0.028, NA	0.012, NA	0.020, NA
	SD, SE	12.2671, 2.8914	8.7453, 1.5460	10.0298, 1.4184	0.0654, 0.0119	0.0133, 0.0022	0.0455, 0.0056
	MEDIAN	6.396	6.606	6.606	0.006	0.012	0.009
	MIN, MAX	0.105, 54.819	0.308, 34.604	0.105, 54.819	0.000, 0.271	0.000, 0.086	0.000, 0.271
	5%, 95%	0.105, 54.819	0.438, 30.831	0.438, 30.831	0.000, 0.253	0.006, 0.018	0.000, 0.074
	BLQ Values Included	0	0	0	18	34	52
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	9.017, 5.588	8.986, 5.553	8.998, 5.566	0.070, NA	0.012, NA	0.039, NA
	SD, SE	9.4091, 2.2178	8.0873, 1.4525	8.4990, 1.2141	0.3236, 0.0591	0.0089, 0.0015	0.2182, 0.0269
	MEDIAN	6.994	7.780	7.780	0.006	0.012	0.006
	MIN, MAX	0.074, 42.637	0.395, 34.709	0.074, 42.637	0.000, 1.782	0.000, 0.049	0.000, 1.782
	5%, 95%	0.074, 42.637	0.438, 28.562	0.438, 28.562	0.000, 0.036	0.006, 0.025	0.000, 0.025
	BLQ Values Included	0	0	0	22	33	55
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	8.580, 4.502	10.277, 7.593	9.650, 6.259	0.009, NA	0.012, 0.011	0.011, NA
	SD, SE	7.1459, 1.7331	7.2033, 1.3380	7.1517, 1.0545	0.0089, 0.0016	0.0069, 0.0012	0.0080, 0.0010
	MEDIAN	7.509	9.204	9.066	0.006	0.012	0.009
	MIN, MAX	0.031, 26.177	0.345, 31.195	0.031, 31.195	0.000, 0.049	0.006, 0.031	0.000, 0.049
	5%, 95%	0.031, 26.177	2.201, 25.751	0.660, 25.751	0.000, 0.018	0.006, 0.031	0.000, 0.025
	BLQ Values Included	0	0	0	23	35	58
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	9.107, 5.684	9.537, 6.362	9.382, 6.109	0.036, NA	0.012, 0.011	0.023, NA
	SD, SE	8.1155, 1.9128	7.6954, 1.3604	7.7691, 1.0987	0.1234, 0.0225	0.0075, 0.0012	0.0834, 0.0103
	MEDIAN	7.627	8.394	8.328	0.007	0.011	0.010
	MIN, MAX	0.070, 36.164	0.373, 33.503	0.070, 36.164	0.000, 0.682	0.002, 0.041	0.000, 0.682
	5%, 95%	0.070, 36.164	0.734, 25.067	0.734, 25.067	0.002, 0.094	0.006, 0.025	0.004, 0.039

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Cotinine (ug/24hr)

Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	4697.130, 3151.040	4980.330, 3583.250	4878.380, 3421.220	7.373, 3.378	3.500, 2.494	5.260, 2.863
	SD, SE	3405.8700, 802.7700	3510.2700, 620.5340	3440.7600, 486.5980	10.9875, 2.0060	4.0651, 0.6775	8.1569, 1.0040
	MEDIAN	4337.910	4470.820	4470.820	1.985	2.449	2.243
	MIN, MAX	44.556, 14394.338	100.100, 17099.775	44.556, 17099.775	0.950, 46.593	0.570, 20.150	0.570, 46.593
	5%, 95%	44.556, 14394.300	720.720, 10349.600	720.720, 10349.600	1.030, 31.240	0.800, 16.174	1.030, 23.940
	BLQ Values Included	0	0	0	11	23	34
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	4529.450, 3076.860	5307.500, 4056.020	5021.690, 3664.560	9.251, 3.780	3.905, 2.849	6.335, 3.240
	SD, SE	2787.8400, 657.1010	3484.5900, 625.8520	3238.0900, 462.5840	17.8779, 3.2640	3.5318, 0.5886	12.5104, 1.5399
	MEDIAN	4738.130	5108.530	5068.690	3.046	2.490	2.745
	MIN, MAX	25.650, 11710.980	240.900, 16352.593	25.650, 16352.593	0.625, 95.190	0.750, 13.755	0.625, 95.190
	5%, 95%	25.650, 11711.000	735.694, 14208.600	735.694, 11711.000	0.820, 27.225	0.915, 12.760	0.915, 17.978
	BLQ Values Included	0	0	0	12	21	33
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	5082.500, 3029.690	5097.600, 4137.160	5092.020, 3687.210	6.551, 3.654	3.148, 2.496	4.695, 2.968
	SD, SE	3857.0400, 935.4700	2623.3500, 487.1440	3093.8100, 456.1580	9.7076, 1.7724	2.8940, 0.4823	7.0334, 0.8657
	MEDIAN	3803.840	5222.570	5049.490	2.654	2.423	2.475
	MIN, MAX	21.379, 13322.126	520.428, 10294.830	21.379, 13322.126	1.350, 43.940	0.990, 15.268	0.990, 43.940
	5%, 95%	21.379, 13322.100	756.280, 9606.210	538.890, 10641.300	1.430, 33.930	1.034, 11.925	1.200, 14.945
	BLQ Values Included	0	0	0	14	26	40
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	4774.450, 3201.350	5005.220, 3905.530	4922.140, 3635.760	7.725, 3.939	3.518, 2.757	5.430, 3.243
	SD, SE	3149.1200, 742.2560	2989.8500, 528.5360	3018.0300, 426.8140	11.0103, 2.0102	2.9605, 0.4934	7.9536, 0.9790
	MEDIAN	4549.290	5168.870	5080.990	2.795	2.623	2.645
	MIN, MAX	30.528, 13142.500	287.143, 12691.100	30.528, 13142.500	1.133, 48.539	0.967, 11.705	0.967, 48.539
	5%, 95%	30.528, 13142.500	834.401, 10962.600	834.401, 10962.600	1.193, 30.177	1.167, 11.541	1.181, 21.198

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 10 of ?)

Biomarker: Total Cotinine (nmol/24hr)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	26656.200, 17882.100	28263.400, 20334.900	27684.800, 19415.400	41.839, 19.170	19.862, 14.154	29.851, 16.247
	SD, SE	19328.3000, 4555.7200	19920.8000, 3521.5300	19526.3000, 2761.4400	62.3538, 11.3842	23.0692, 3.8449	46.2905, 5.6980
	MEDIAN	24617.600	25371.900	25371.900	11.265	13.895	12.727
	MIN, MAX	252.855, 81687.868	568.068, 97041.223	252.855, 97041.223	5.391, 264.415	3.235, 114.351	3.235, 264.415
	5%, 95%	252.855, 81687.900	4090.090, 58734.100	4090.090, 58734.100	5.845, 177.287	4.540, 91.787	5.845, 135.860
	BLQ Values Included	0	0	0	11	23	34
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	25704.700, 17461.200	30120.100, 23017.900	28498.100, 20796.400	52.500, 21.453	22.163, 16.167	35.952, 18.386
	SD, SE	15821.0000, 3729.0500	19775.1000, 3551.7100	18376.2000, 2625.1700	101.4570, 18.5234	20.0431, 3.3405	70.9965, 8.7391
	MEDIAN	26888.900	28990.900	28764.800	17.287	14.131	15.578
	MIN, MAX	145.564, 66459.812	1367.108, 92800.965	145.564, 92800.965	3.547, 540.203	4.256, 78.060	3.547, 540.203
	5%, 95%	145.564, 66459.800	4175.060, 80634.100	4175.060, 66459.800	4.654, 154.502	5.193, 72.413	5.193, 102.025
	BLQ Values Included	0	0	0	12	21	33
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	28843.200, 17193.500	28928.900, 23478.400	28897.200, 20924.900	37.175, 20.737	17.867, 14.163	26.643, 16.843
	SD, SE	21888.7000, 5308.7900	14887.5000, 2764.5400	17557.4000, 2588.7000	55.0906, 10.0581	16.4231, 2.7372	39.9143, 4.9131
	MEDIAN	21586.800	29638.100	28655.900	15.062	13.748	14.046
	MIN, MAX	121.326, 75603.065	2953.429, 58423.160	121.326, 75603.065	7.661, 249.360	5.618, 86.646	5.618, 249.360
	5%, 95%	121.326, 75603.100	4291.890, 54515.200	3058.200, 60389.500	8.115, 192.553	5.868, 67.674	6.810, 84.813
	BLQ Values Included	0	0	0	14	26	40
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	27095.000, 18167.700	28404.600, 22163.900	27933.100, 20632.900	43.838, 22.354	19.964, 15.647	30.816, 18.402
	SD, SE	17871.3000, 4212.3000	16967.4000, 2999.4400	17127.3000, 2422.1700	62.4834, 11.4079	16.8006, 2.8001	45.1369, 5.5560
	MEDIAN	25817.200	29333.300	28834.600	15.859	14.885	15.009
	MIN, MAX	173.248, 74583.600	1629.540, 72021.900	173.248, 74583.600	6.432, 275.461	5.486, 66.424	5.486, 275.461
	5%, 95%	173.248, 74583.600	4735.230, 62212.600	4735.230, 62212.600	6.772, 171.255	6.621, 65.497	6.704, 120.299

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Cotinine (ng/mg Creatinine)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	3.409, 2.384	4.265, 3.125	3.957, 2.835	0.005, NA	0.003, NA	0.004, NA
	SD, SE	2.1337, 0.5029	2.5826, 0.4565	2.4437, 0.3456	0.0074, 0.0014	0.0035, 0.0006	0.0056, 0.0007
	MEDIAN	3.233	4.284	3.861	0.001	0.002	0.002
	MIN, MAX	0.042, 8.403	0.083, 10.371	0.042, 10.371	0.000, 0.033	0.000, 0.015	0.000, 0.033
	5%, 95%	0.042, 8.403	0.473, 8.958	0.473, 8.403	0.001, 0.021	0.001, 0.014	0.001, 0.015
Week 2	BLQ Values Included	0	0	0	11	23	34
	N	18	31	49	30	36	66
	MEAN, GEO MEAN	3.265, 2.263	4.176, 3.220	3.842, 2.829	0.007, NA	0.003, 0.002	0.005, NA
	SD, SE	1.9738, 0.4652	2.7789, 0.4991	2.5305, 0.3615	0.0164, 0.0030	0.0030, 0.0005	0.0113, 0.0014
	MEDIAN	2.968	3.723	3.699	0.002	0.002	0.002
	MIN, MAX	0.029, 7.522	0.240, 12.831	0.029, 12.831	0.000, 0.091	0.001, 0.015	0.000, 0.091
Week 3	5%, 95%	0.029, 7.522	0.636, 9.853	0.636, 8.239	0.001, 0.015	0.001, 0.009	0.001, 0.014
	BLQ Values Included	0	0	0	12	21	33
	N	17	29	46	30	36	66
	MEAN, GEO MEAN	3.363, 2.188	4.440, 3.529	4.042, 2.957	0.004, 0.002	0.003, 0.002	0.003, 0.002
	SD, SE	2.1802, 0.5288	2.7980, 0.5196	2.6149, 0.3855	0.0054, 0.0010	0.0034, 0.0006	0.0044, 0.0005
	MEDIAN	2.961	3.807	3.681	0.002	0.002	0.002
Overall*	MIN, MAX	0.019, 7.284	0.518, 11.859	0.019, 11.859	0.001, 0.025	0.001, 0.020	0.001, 0.025
	5%, 95%	0.019, 7.284	0.832, 10.517	0.832, 9.415	0.001, 0.019	0.001, 0.008	0.001, 0.008
	BLQ Values Included	0	0	0	14	26	40
	N	18	32	50	30	36	66
	MEAN, GEO MEAN	3.344, 2.331	4.291, 3.340	3.950, 2.935	0.005, 0.002	0.003, 0.002	0.004, 0.002
	SD, SE	2.0124, 0.4743	2.6178, 0.4628	2.4395, 0.3450	0.0083, 0.0015	0.0030, 0.0005	0.0060, 0.0007
Overall*	MEDIAN	3.191	3.974	3.804	0.002	0.002	0.002
	MIN, MAX	0.030, 7.123	0.280, 10.694	0.030, 10.694	0.001, 0.042	0.001, 0.015	0.001, 0.042
	5%, 95%	0.030, 7.123	0.733, 8.923	0.733, 8.810	0.001, 0.018	0.001, 0.010	0.001, 0.015
	BLQ Values Included	0	0	0	14	26	40

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Cotinine (nmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	19.343, 13.527	24.206, 17.733	22.456, 16.086	0.026, NA	0.017, NA	0.021, NA
	SD, SE	12.1086, 2.8540	14.6561, 2.5908	13.8680, 1.9612	0.0420, 0.0077	0.0199, 0.0033	0.0319, 0.0039
	MEDIAN	18.345	24.309	21.912	0.006	0.011	0.011
	MIN, MAX	0.238, 47.687	0.471, 58.855	0.238, 58.855	0.000, 0.187	0.000, 0.085	0.000, 0.187
	5%, 95%	0.238, 47.687	2.684, 50.837	2.684, 47.687	0.006, 0.119	0.006, 0.079	0.006, 0.085
Week 2	BLQ Values Included	0	0	0	11	23	34
	N	18	31	49	30	36	66
	MEAN, GEO MEAN	18.530, 12.843	23.701, 18.276	21.801, 16.055	0.038, NA	0.019, 0.014	0.028, NA
	SD, SE	11.2015, 2.6402	15.7703, 2.8324	14.3604, 2.0515	0.0932, 0.0170	0.0171, 0.0028	0.0642, 0.0079
	MEDIAN	16.841	21.128	20.992	0.009	0.011	0.011
	MIN, MAX	0.165, 42.687	1.362, 72.816	0.165, 72.816	0.000, 0.516	0.006, 0.085	0.000, 0.516
Week 3	5%, 95%	0.165, 42.687	3.609, 55.916	3.609, 46.756	0.006, 0.085	0.006, 0.051	0.006, 0.079
	BLQ Values Included	0	0	0	12	21	33
	N	17	29	46	30	36	66
	MEAN, GEO MEAN	19.086, 12.417	25.199, 20.024	22.940, 16.783	0.021, 0.012	0.017, 0.013	0.019, 0.013
	SD, SE	12.3729, 3.0009	15.8784, 2.9485	14.8394, 2.1880	0.0306, 0.0056	0.0194, 0.0032	0.0250, 0.0031
	MEDIAN	16.804	21.605	20.887	0.011	0.011	0.011
Overall*	MIN, MAX	0.108, 41.337	2.940, 67.300	0.108, 67.300	0.006, 0.142	0.006, 0.114	0.006, 0.142
	5%, 95%	0.108, 41.337	4.722, 59.684	4.722, 53.430	0.006, 0.108	0.006, 0.045	0.006, 0.045
	BLQ Values Included	0	0	0	14	26	40
	N	18	32	50	30	36	66
	MEAN, GEO MEAN	18.974, 13.230	24.354, 18.957	22.417, 16.655	0.028, 0.014	0.018, 0.014	0.023, 0.014
	SD, SE	11.4205, 2.6918	14.8558, 2.6262	13.8448, 1.9579	0.0475, 0.0087	0.0168, 0.0028	0.0344, 0.0042
Overall*	MEDIAN	18.107	22.550	21.585	0.010	0.011	0.011
	MIN, MAX	0.170, 40.425	1.591, 60.690	0.170, 60.690	0.004, 0.240	0.004, 0.085	0.004, 0.240
	5%, 95%	0.170, 40.425	4.162, 50.636	4.162, 49.999	0.004, 0.104	0.006, 0.057	0.006, 0.085

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Cotinine (ug/24hr)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1683.980, 1226.760	1833.760, 1377.870	1779.840, 1321.430	4.187, 2.268	2.264, 1.955	3.138, 2.091
	SD, SE	920.8080, 217.0360	1274.5200, 225.3050	1152.0100, 162.9180	6.2628, 1.1434	1.3867, 0.2311	4.4120, 0.5431
	MEDIAN	1908.820	1583.010	1795.820	1.830	1.925	1.915
	MIN, MAX	26.790, 3201.831	50.050, 6435.660	26.790, 6435.660	0.530, 27.900	0.570, 6.912	0.530, 27.900
	5%, 95%	26.790, 3201.830	308.979, 3606.940	308.979, 3580.190	0.715, 20.140	0.800, 6.825	0.780, 12.160
	BLQ Values Included	0	0	0	19	31	50
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	1784.290, 1256.440	1837.170, 1433.920	1817.750, 1365.990	5.196, 2.549	2.402, 2.103	3.672, 2.295
	SD, SE	902.3150, 212.6780	1174.1100, 210.8760	1072.6600, 153.2370	10.7544, 1.9635	1.3361, 0.2227	7.3843, 0.9089
	MEDIAN	1769.270	1686.630	1731.970	1.917	2.205	2.180
	MIN, MAX	13.950, 3133.273	148.738, 4366.890	13.950, 4366.890	0.625, 59.280	0.660, 7.795	0.625, 59.280
	5%, 95%	13.950, 3133.270	350.900, 4252.950	226.118, 3766.020	0.815, 13.221	0.750, 4.875	0.815, 9.804
	BLQ Values Included	0	0	0	18	30	48
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	2040.610, 1231.980	1902.950, 1558.720	1953.820, 1428.930	3.809, 2.464	2.267, 2.071	2.968, 2.241
	SD, SE	1576.8000, 382.4300	1132.3100, 210.2650	1298.5800, 191.4640	5.2300, 0.9549	1.0719, 0.1786	3.6635, 0.4509
	MEDIAN	1600.540	1655.220	1633.050	2.032	2.050	2.050
	MIN, MAX	6.393, 5162.740	225.246, 4886.167	6.393, 5162.740	0.750, 25.870	0.940, 6.420	0.750, 25.870
	5%, 95%	6.393, 5162.740	391.688, 3866.580	354.936, 4856.040	1.072, 15.370	0.990, 4.740	1.068, 7.188
	BLQ Values Included	0	0	0	18	33	51
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1830.020, 1303.960	1818.890, 1460.500	1822.900, 1402.090	4.397, 2.599	2.311, 2.100	3.259, 2.313
	SD, SE	1019.6400, 240.3310	1095.3400, 193.6300	1058.1900, 149.6500	6.2744, 1.1455	1.0528, 0.1755	4.3883, 0.5402
	MEDIAN	1786.240	1681.960	1695.440	1.991	2.187	2.147
	MIN, MAX	15.711, 3774.690	141.345, 4483.280	15.711, 4483.280	0.787, 30.043	0.967, 5.145	0.787, 30.043
	5%, 95%	15.711, 3774.690	374.266, 3982.290	374.266, 3774.690	1.092, 16.027	0.980, 4.770	1.092, 12.202

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Cotinine (nmol/24hr)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	9556.570, 6961.840	10406.600, 7819.390	10100.600, 7499.140	23.762, 12.871	12.849, 11.094	17.809, 11.869
	SD, SE	5225.5800, 1231.6800	7232.8800, 1278.6100	6537.6300, 924.5610	35.5415, 6.4890	7.8697, 1.3116	25.0383, 3.0820
	MEDIAN	10832.500	8983.560	10191.300	10.383	10.925	10.868
	MIN, MAX	152.033, 18170.391	284.034, 36522.371	152.033, 36522.371	3.008, 158.333	3.235, 39.226	3.008, 158.333
	5%, 95%	152.033, 18170.400	1753.460, 20469.400	1753.460, 20317.600	4.058, 114.295	4.540, 38.732	4.427, 69.008
Week 2	BLQ Values Included	0	0	0	19	31	50
	N	18	31	49	30	36	66
	MEAN, GEO MEAN	10125.800, 7130.290	10426.000, 8137.520	10315.700, 7751.970	29.490, 14.465	13.633, 11.936	20.841, 13.025
	SD, SE	5120.6400, 1206.9500	6663.0700, 1196.7200	6087.3400, 869.6210	61.0312, 11.1427	7.5825, 1.2637	41.9057, 5.1582
	MEDIAN	10040.600	9571.630	9828.950	10.879	12.514	12.372
	MIN, MAX	79.166, 17781.324	844.088, 24782.101	79.166, 24782.101	3.547, 336.414	3.746, 44.237	3.547, 336.414
Week 3	5%, 95%	79.166, 17781.300	1991.360, 24135.500	1283.220, 21372.200	4.625, 75.029	4.256, 27.666	4.625, 55.638
	BLQ Values Included	0	0	0	18	30	48
	N	17	29	46	30	36	66
	MEAN, GEO MEAN	11580.500, 6991.470	10799.200, 8845.710	11087.900, 8109.170	21.615, 13.985	12.863, 11.752	16.841, 12.719
	SD, SE	8948.3300, 2170.2900	6425.8600, 1193.2500	7369.4100, 1086.5600	29.6804, 5.4189	6.0828, 1.0138	20.7903, 2.5591
	MEDIAN	9083.040	9393.370	9267.540	11.532	11.634	11.634
Overall*	MIN, MAX	36.280, 29298.550	1278.271, 27728.998	36.280, 29298.550	4.256, 146.812	5.335, 36.434	4.256, 146.812
	5%, 95%	36.280, 29298.600	2222.830, 21942.800	2014.260, 27558.000	6.084, 87.225	5.618, 26.900	6.061, 40.792
	BLQ Values Included	0	0	0	18	33	51
	N	18	32	50	30	36	66
	MEAN, GEO MEAN	10385.400, 7399.990	10322.200, 8288.310	10344.900, 7956.860	24.956, 14.747	13.115, 11.915	18.497, 13.128
	SD, SE	5786.4600, 1363.8800	6216.0300, 1098.8500	6005.2200, 849.2660	35.6075, 6.5010	5.9749, 0.9958	24.9037, 3.0654
Overall*	MEDIAN	10136.900	9545.130	9621.610	11.298	12.409	12.182
	MIN, MAX	89.160, 21421.400	802.131, 25442.600	89.160, 25442.600	4.464, 170.496	5.486, 29.198	4.464, 170.496
	5%, 95%	89.160, 21421.400	2123.960, 22599.500	2123.960, 21421.400	6.195, 90.955	5.562, 27.068	6.195, 69.245

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Cotinine (ug/mg Creatinin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1.448, 0.928	1.697, 1.202	1.607, 1.095	0.003, NA	0.002, NA	0.002, NA
	SD, SE	1.3218, 0.3115	1.1734, 0.2074	1.2214, 0.1727	0.0041, 0.0008	0.0016, 0.0003	0.0030, 0.0004
	MEDIAN	1.260	1.628	1.401	0.001	0.002	0.002
	MIN, MAX	0.025, 5.808	0.042, 4.207	0.025, 5.808	0.000, 0.020	0.000, 0.010	0.000, 0.020
	5%, 95%	0.025, 5.808	0.203, 3.903	0.203, 3.903	0.000, 0.010	0.001, 0.005	0.000, 0.009
	BLQ Values Included	0	0	0	19	31	50
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	1.431, 0.925	1.499, 1.139	1.474, 1.055	0.004, NA	0.002, NA	0.003, NA
	SD, SE	1.1733, 0.2765	1.0524, 0.1890	1.0867, 0.1552	0.0102, 0.0019	0.0014, 0.0002	0.0070, 0.0009
	MEDIAN	1.264	1.250	1.263	0.001	0.002	0.002
	MIN, MAX	0.016, 5.177	0.148, 4.123	0.016, 5.177	0.000, 0.057	0.000, 0.007	0.000, 0.057
	5%, 95%	0.016, 5.177	0.275, 3.337	0.148, 3.337	0.000, 0.007	0.001, 0.005	0.000, 0.007
	BLQ Values Included	0	0	0	18	30	48
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	1.378, 0.893	1.745, 1.329	1.609, 1.147	0.002, NA	0.002, 0.002	0.002, NA
	SD, SE	0.9164, 0.2223	1.3149, 0.2442	1.1859, 0.1749	0.0028, 0.0005	0.0016, 0.0003	0.0022, 0.0003
	MEDIAN	1.292	1.410	1.333	0.001	0.002	0.002
	MIN, MAX	0.006, 3.315	0.224, 5.186	0.006, 5.186	0.000, 0.014	0.001, 0.009	0.000, 0.014
	5%, 95%	0.006, 3.315	0.383, 4.641	0.383, 4.005	0.000, 0.009	0.001, 0.005	0.001, 0.005
	BLQ Values Included	0	0	0	18	33	51
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1.412, 0.957	1.666, 1.253	1.575, 1.138	0.003, NA	0.002, NA	0.002, NA
	SD, SE	1.0606, 0.2500	1.1632, 0.2056	1.1231, 0.1588	0.0049, 0.0009	0.0013, 0.0002	0.0034, 0.0004
	MEDIAN	1.295	1.349	1.305	0.001	0.002	0.002
	MIN, MAX	0.016, 4.572	0.138, 4.505	0.016, 4.572	0.000, 0.026	0.000, 0.006	0.000, 0.026
	5%, 95%	0.016, 4.572	0.266, 3.886	0.266, 3.886	0.001, 0.009	0.001, 0.006	0.001, 0.007

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Cotinine (nmol/mg Creatin)

Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	8.216, 5.264	9.630, 6.822	9.121, 6.214	0.015, NA	0.012, NA	0.013, NA
	SD, SE	7.5011, 1.7680	6.6590, 1.1772	6.9314, 0.9802	0.0234, 0.0043	0.0092, 0.0015	0.0172, 0.0021
	MEDIAN	7.151	9.239	7.951	0.006	0.011	0.009
	MIN, MAX	0.142, 32.960	0.238, 23.875	0.142, 32.960	0.000, 0.114	0.000, 0.057	0.000, 0.114
	5%, 95%	0.142, 32.960	1.152, 22.150	1.152, 22.150	0.000, 0.057	0.006, 0.028	0.000, 0.051
	BLQ Values Included	0	0	0	19	31	50
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	8.122, 5.249	8.506, 6.461	8.365, 5.987	0.022, NA	0.012, NA	0.017, NA
	SD, SE	6.6582, 1.5693	5.9724, 1.0727	6.1668, 0.8810	0.0577, 0.0105	0.0081, 0.0013	0.0394, 0.0048
	MEDIAN	7.174	7.094	7.168	0.006	0.011	0.011
	MIN, MAX	0.091, 29.379	0.840, 23.398	0.091, 29.379	0.000, 0.323	0.000, 0.040	0.000, 0.323
	5%, 95%	0.091, 29.379	1.561, 18.937	0.840, 18.937	0.000, 0.040	0.006, 0.028	0.000, 0.040
	BLQ Values Included	0	0	0	18	30	48
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	7.819, 5.065	9.903, 7.544	9.133, 6.511	0.012, NA	0.012, 0.010	0.012, NA
	SD, SE	5.2007, 1.2614	7.4619, 1.3856	6.7302, 0.9923	0.0158, 0.0029	0.0090, 0.0015	0.0124, 0.0015
	MEDIAN	7.332	8.002	7.565	0.006	0.011	0.011
	MIN, MAX	0.034, 18.813	1.271, 29.431	0.034, 29.431	0.000, 0.079	0.006, 0.051	0.000, 0.079
	5%, 95%	0.034, 18.813	2.174, 26.338	2.174, 22.728	0.000, 0.051	0.006, 0.028	0.006, 0.028
	BLQ Values Included	0	0	0	18	33	51
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	8.016, 5.428	9.455, 7.113	8.937, 6.454	0.017, NA	0.012, 0.010	0.014, NA
	SD, SE	6.0188, 1.4186	6.6015, 1.1670	6.3738, 0.9014	0.0278, 0.0051	0.0073, 0.0012	0.0195, 0.0024
	MEDIAN	7.346	7.653	7.403	0.008	0.010	0.009
	MIN, MAX	0.089, 25.944	0.783, 25.568	0.089, 25.944	0.000, 0.149	0.002, 0.036	0.000, 0.149
	5%, 95%	0.089, 25.944	1.510, 22.053	1.510, 22.053	0.004, 0.051	0.006, 0.032	0.004, 0.038

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total 3-hydroxycotinine (ug/24hr)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	8481.670, 5058.790	7465.200, 5530.510	7831.130, 5355.820	12.639, 5.259	4.573, 3.077	8.239, 3.926
	SD, SE	7495.8000, 1766.7800	5073.8600, 896.9410	6001.9500, 848.8040	19.7909, 3.6133	5.4679, 0.9113	14.3955, 1.7720
	MEDIAN	7795.660	7094.740	7518.910	5.555	2.763	2.948
	MIN, MAX	80.370, 31233.615	185.625, 21231.840	80.370, 31233.615	0.950, 84.568	0.800, 25.920	0.800, 84.568
	5%, 95%	80.370, 31233.600	1264.620, 17386.200	795.900, 18631.300	1.030, 59.985	1.140, 19.728	1.140, 40.870
	BLQ Values Included	0	0	0	8	16	24
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	7771.090, 5070.700	9033.250, 6974.020	8569.600, 6203.500	18.479, 6.526	5.572, 3.656	11.439, 4.758
	SD, SE	5217.2100, 1229.7100	5553.5400, 997.4450	5412.4100, 773.2020	36.8337, 6.7249	6.2324, 1.0387	25.8488, 3.1818
	MEDIAN	7298.240	8284.170	7610.060	3.674	2.848	3.038
	MIN, MAX	48.420, 20994.570	504.248, 22147.192	48.420, 22147.192	1.000, 191.422	1.050, 24.208	1.000, 191.422
	5%, 95%	48.420, 20994.600	1171.890, 19677.600	842.508, 19677.600	1.023, 74.670	1.240, 23.013	1.148, 43.240
	BLQ Values Included	0	0	0	2	14	16
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	8564.710, 4903.590	8436.230, 6644.600	8483.710, 5938.860	12.223, 5.533	4.322, 3.155	7.913, 4.073
	SD, SE	7430.9800, 1802.2800	5351.4100, 993.7310	6120.1700, 902.3690	20.2196, 3.6916	4.3514, 0.7252	14.4330, 1.7766
	MEDIAN	6563.700	7278.860	6586.050	3.665	2.885	3.210
	MIN, MAX	52.295, 27454.900	1258.180, 19074.831	52.295, 27454.900	1.430, 89.830	1.068, 21.688	1.068, 89.830
	5%, 95%	52.295, 27454.900	1308.320, 17880.000	1258.180, 18489.900	1.720, 55.313	1.089, 14.840	1.350, 44.835
	BLQ Values Included	0	0	0	7	19	26
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	8308.190, 5267.650	8107.260, 6415.480	8179.590, 5975.970	14.447, 6.474	4.822, 3.520	9.197, 4.643
	SD, SE	6258.3500, 1475.1100	5035.7700, 890.2060	5444.3900, 769.9540	22.2395, 4.0604	4.5465, 0.7578	15.9724, 1.9661
	MEDIAN	6721.080	7035.320	6813.150	5.076	2.858	3.307
	MIN, MAX	60.362, 23472.700	666.066, 20818.000	60.362, 23472.700	1.318, 97.065	1.067, 20.305	1.067, 97.065
	5%, 95%	60.362, 23472.700	1386.130, 16456.700	827.503, 20711.600	1.374, 66.991	1.303, 18.212	1.355, 42.982

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total 3-hydroxycotinine (nmol/24hr)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	44130.100, 26320.900	38841.400, 28775.200	40745.400, 27866.300	65762, 27.363	23.791, 16.009	42.869, 20.426
	SD, SE	39000.6000, 9192.5400	26399.3000, 4666.7800	31228.2000, 4416.3300	102.9720, 18.8001	28.4498, 4.7416	74.8998, 9.2195
	MEDIAN	40560.800	36913.900	39120.900	18.497	14.373	15.336
	MIN, MAX	418.165, 162508.499	965.807, 110469.264	418.165, 162508.499	4.943, 440.007	4.162, 134.862	4.162, 440.007
	5%, 95%	418.165, 162508.000	6579.820, 90460.300	4141.070, 96938.400	5.359, 312.102	5.931, 102.645	5.931, 212.647
	BLQ Values Included	0	0	0	8	16	24
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	40433.000, 26382.900	47000.000, 36285.800	44587.600, 32276.800	96.144, 33.953	28.991, 19.024	59.515, 24.754
	SD, SE	27145.1000, 6398.1700	28895.1000, 5189.7000	28160.8000, 4022.9700	191.6460, 34.9896	32.4272, 5.4045	134.4910, 16.5547
	MEDIAN	37972.700	43102.500	39595.200	19.113	14.816	15.804
	MIN, MAX	251.929, 109234.748	2623.602, 115231.840	251.929, 115231.840	5.203, 995.969	5.463, 125.954	5.203, 995.969
	5%, 95%	251.929, 109235.000	6097.320, 102382.000	4383.570, 102382.000	5.323, 388.508	6.452, 119.737	5.973, 224.978
	BLQ Values Included	0	0	0	2	14	16
Week 3	N	17	29	45	30	36	66
	MEAN, GEO MEAN	44562.200, 25513.400	43893.700, 34571.800	44140.700, 30899.900	63.595, 28.790	22.485, 16.417	41.171, 21.193
	SD, SE	38663.4000, 9377.2500	27843.4000, 5170.3800	31843.2000, 4695.0300	105.2020, 19.2072	22.6402, 3.7734	75.0951, 9.2436
	MEDIAN	34150.900	37871.900	34267.200	19.069	15.011	16.699
	MIN, MAX	272.091, 142847.845	6546.311, 99246.345	272.091, 142847.845	7.440, 467.385	5.557, 112.843	5.557, 467.385
	5%, 95%	272.091, 142848.000	6807.210, 93029.900	6546.310, 95202.800	8.949, 287.794	5.666, 77.213	7.024, 233.277
	BLQ Values Included	0	0	0	7	19	26
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	43227.600, 27407.600	42182.100, 33379.700	42558.500, 31093.000	75.167, 33.685	25.089, 18.313	47.852, 24.159
	SD, SE	32562.3000, 7675.0200	26201.1000, 4631.7400	28327.2000, 4006.0800	115.7120, 21.1260	23.6560, 3.9427	83.1043, 10.2294
	MEDIAN	34969.800	36604.800	35448.800	26.410	14.872	17.204
	MIN, MAX	314.062, 122129.000	3465.540, 108316.000	314.062, 122129.000	6.859, 505.029	5.550, 105.649	5.550, 505.029
	5%, 95%	314.062, 122129.000	7212.010, 85624.400	4305.500, 107763.000	7.151, 348.552	6.778, 94.757	7.048, 223.634

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234' for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total 3-hydroxycotinine (ug/mg Creatinin)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	5.847, 3.827	6.788, 4.823	6.449, 4.438	0.008, NA	0.004, 0.003	0.006, NA
	SD, SE	4.1160, 0.9701	4.9747, 0.8794	4.6629, 0.6594	0.0122, 0.0022	0.0068, 0.0011	0.0097, 0.0012
	MEDIAN	5.353	5.406	5.375	0.002	0.002	0.002
	MIN, MAX	0.076, 15.997	0.154, 18.383	0.076, 18.383	0.000, 0.052	0.001, 0.037	0.000, 0.052
	5%, 95%	0.076, 15.997	0.676, 18.231	0.370, 15.997	0.001, 0.042	0.001, 0.022	0.001, 0.022
	BLQ Values Included	0	0	0	8	16	24
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	5.688, 3.726	7.402, 5.538	6.772, 4.788	0.011, NA	0.005, 0.003	0.008, NA
	SD, SE	4.0901, 0.9640	5.3130, 0.9542	4.9259, 0.7037	0.0217, 0.0040	0.0059, 0.0010	0.0155, 0.0019
	MEDIAN	4.759	5.898	5.554	0.004	0.002	0.003
	MIN, MAX	0.054, 15.619	0.503, 20.024	0.054, 20.024	0.000, 0.099	0.001, 0.027	0.000, 0.099
	5%, 95%	0.054, 15.619	0.918, 18.908	0.503, 18.134	0.001, 0.071	0.001, 0.021	0.001, 0.027
	BLQ Values Included	0	0	0	2	14	16
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	5.880, 3.539	7.537, 5.667	6.924, 4.762	0.006, 0.003	0.004, 0.003	0.005, 0.003
	SD, SE	4.7052, 1.1412	5.6364, 1.0466	5.3191, 0.7843	0.0104, 0.0019	0.0049, 0.0008	0.0079, 0.0010
	MEDIAN	5.037	4.992	5.015	0.002	0.002	0.002
	MIN, MAX	0.046, 17.626	1.148, 23.294	0.046, 23.294	0.001, 0.050	0.001, 0.029	0.001, 0.050
	5%, 95%	0.046, 17.626	1.303, 17.524	1.148, 17.524	0.001, 0.026	0.001, 0.010	0.001, 0.021
	BLQ Values Included	0	0	0	7	19	26
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	5.814, 3.797	7.186, 5.455	6.692, 4.787	0.008, 0.004	0.004, 0.003	0.006, 0.003
	SD, SE	4.1774, 0.9846	5.1148, 0.9042	4.8008, 0.6789	0.0125, 0.0023	0.0052, 0.0009	0.0094, 0.0012
	MEDIAN	4.913	5.573	5.297	0.003	0.003	0.003
	MIN, MAX	0.059, 16.414	0.653, 20.195	0.059, 20.195	0.001, 0.046	0.001, 0.026	0.001, 0.046
	5%, 95%	0.059, 16.414	0.914, 17.186	0.553, 16.414	0.001, 0.039	0.001, 0.021	0.001, 0.026

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total 3-hydroxycotinine (nmol/mg Creatin)

Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	30.420, 19.913	35.319, 25.093	33.556, 23.089	0.039, NA	0.023, 0.014	0.030, NA
	SD, SE	21.4154, 5.0476	25.8835, 4.5756	24.2611, 3.4310	0.0638, 0.0116	0.0354, 0.0059	0.0506, 0.0062
	MEDIAN	27.849	28.128	27.964	0.010	0.010	0.010
	MIN, MAX	0.395, 83.232	0.801, 95.647	0.395, 95.647	0.000, 0.271	0.005, 0.193	0.000, 0.271
	5%, 95%	0.395, 83.232	3.517, 94.856	1.925, 83.232	0.005, 0.219	0.005, 0.114	0.005, 0.114
Week 2	BLQ Values Included	0	0	0	8	16	24
	N	18	31	49	30	36	66
	MEAN, GEO MEAN	29.593, 19.388	38.511, 28.813	35.235, 24.911	0.059, NA	0.025, 0.015	0.040, NA
	SD, SE	21.2809, 5.0160	27.6433, 4.9649	25.6293, 3.6613	0.1128, 0.0206	0.0310, 0.0052	0.0805, 0.0099
	MEDIAN	24.761	30.687	28.897	0.019	0.010	0.013
	MIN, MAX	0.281, 81.266	2.617, 104.185	0.281, 104.185	0.000, 0.515	0.005, 0.140	0.000, 0.515
Week 3	5%, 95%	0.281, 81.266	4.776, 98.378	2.617, 94.351	0.005, 0.369	0.005, 0.109	0.005, 0.140
	BLQ Values Included	0	0	0	2	14	16
	N	17	29	46	30	36	66
	MEAN, GEO MEAN	30.593, 18.410	39.214, 29.486	36.028, 24.775	0.032, 0.015	0.021, 0.014	0.026, 0.015
	SD, SE	24.4813, 5.9376	29.3260, 5.4457	27.6752, 4.0805	0.0541, 0.0099	0.0258, 0.0043	0.0412, 0.0051
	MEDIAN	26.208	25.973	26.091	0.010	0.010	0.010
Overall*	MIN, MAX	0.239, 91.708	5.973, 121.199	0.239, 121.199	0.005, 0.260	0.005, 0.151	0.005, 0.260
	5%, 95%	0.239, 91.708	6.780, 91.177	5.973, 91.177	0.005, 0.135	0.005, 0.052	0.005, 0.109
	BLQ Values Included	0	0	0	7	19	26
	N	18	32	50	30	36	66
	MEAN, GEO MEAN	30.249, 19.747	37.388, 28.380	34.818, 24.906	0.043, 0.020	0.023, 0.016	0.032, 0.017
	SD, SE	21.7351, 5.1230	26.6119, 4.7044	24.9784, 3.5325	0.0652, 0.0119	0.0271, 0.0045	0.0490, 0.0060
Overall*	MEDIAN	25.563	28.996	27.557	0.016	0.014	0.016
	MIN, MAX	0.305, 85.402	3.399, 105.075	0.305, 105.075	0.003, 0.241	0.005, 0.135	0.003, 0.241
	5%, 95%	0.305, 85.402	4.755, 89.417	3.399, 85.402	0.005, 0.203	0.005, 0.111	0.005, 0.135

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free 3-hydroxycotinine (ug/24hr)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	5856.480, 3547.470	5682.970, 4198.040	5745.430, 3951.120	10.326, 4.671	4.009, 2.796	6.880, 3.530
	SD, SE	4830.8700, 1138.6500	4115.0900, 727.4520	4337.8600, 613.4660	15.7543, 2.8763	4.7488, 0.7915	11.5292, 1.4191
	MEDIAN	5526.840	5379.730	5379.730	3.426	2.722	2.763
	MIN, MAX	42.441, 20367.215	143.550, 18150.580	42.441, 20367.215	0.950, 67.936	0.855, 25.488	0.855, 67.936
	5%, 95%	42.441, 20367.200	935.760, 15778.200	645.000, 15778.200	1.030, 46.035	0.880, 13.974	1.030, 30.820
	BLQ Values Included	0	0	0	7	16	23
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	5893.470, 3777.180	7035.350, 5370.170	6615.880, 4719.000	14.811, 5.527	4.440, 3.244	9.154, 4.133
	SD, SE	3983.1000, 938.8260	4427.2700, 795.1610	4263.6400, 609.0920	29.3232, 5.3537	4.2878, 0.7146	20.5086, 2.5244
	MEDIAN	5281.350	6880.830	6368.090	3.474	2.808	2.918
	MIN, MAX	24.210, 16978.770	400.405, 18154.368	24.210, 18154.368	0.875, 152.550	0.750, 20.909	0.750, 152.550
	5%, 95%	24.210, 16978.800	884.631, 15032.800	722.866, 15032.800	0.902, 60.135	1.240, 13.650	1.023, 31.960
	BLQ Values Included	0	0	0	3	15	18
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	6143.550, 3478.250	6186.920, 4948.810	6170.890, 4344.160	9.735, 4.823	3.727, 2.871	6.458, 3.634
	SD, SE	4990.3900, 1210.3500	3791.4800, 704.0600	4218.9800, 622.0550	15.6351, 2.8546	3.3529, 0.5588	11.1448, 1.3718
	MEDIAN	4755.720	5478.480	5068.950	2.971	2.743	2.894
	MIN, MAX	21.379, 15121.480	976.686, 13569.448	21.379, 15121.480	1.430, 72.800	0.990, 16.830	0.990, 72.800
	5%, 95%	21.379, 15121.500	1154.780, 13029.400	976.686, 14222.600	1.720, 38.750	1.068, 10.528	1.300, 31.610
	BLQ Values Included	0	0	0	8	23	31
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	5997.370, 3797.210	6148.120, 4856.530	6093.850, 4444.840	11.624, 5.555	4.059, 3.182	7.498, 4.099
	SD, SE	4284.2000, 1009.8000	3849.6400, 680.5270	3968.4900, 561.2300	17.7183, 3.2349	3.2903, 0.5484	12.6611, 1.5585
	MEDIAN	5057.480	5453.020	5310.140	4.401	2.830	3.179
	MIN, MAX	29.343, 17222.200	506.880, 16339.400	29.343, 17222.200	1.277, 76.940	1.038, 14.818	1.038, 76.940
	5%, 95%	29.343, 17222.200	991.725, 12433.200	696.229, 12433.200	1.374, 56.114	1.276, 13.701	1.303, 33.167

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free 3-hydroxycotinine (nmol/24hr)

Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	30471.300, 18457.500	29568.500, 21842.400	29893.500, 20557.700	53.724, 24.303	20.857, 14.546	35.797, 18.368
	SD, SE	25135.0000, 5924.3800	21410.8000, 3784.9300	22569.9000, 3191.8600	81.9694, 14.9655	24.7082, 4.1180	59.9865, 7.3838
	MEDIAN	28756.100	27990.700	27990.700	17.826	14.160	14.373
	MIN, MAX	220.821, 105970.620	746.891, 94437.468	220.821, 105970.620	4.943, 353.471	4.449, 132.614	4.449, 353.471
	5%, 95%	220.821, 105971.000	4868.760, 82094.200	3355.940, 82094.200	5.359, 239.520	4.579, 72.707	5.359, 160.356
	BLQ Values Included	0	0	0	7	16	23
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	30663.700, 19652.700	36604.900, 27941.000	34422.400, 24553.000	77.063, 28.756	23.103, 16.880	47.631, 21.505
	SD, SE	20724.1000, 4884.7100	23035.1000, 4137.2200	22183.7000, 3169.1100	152.5690, 27.8551	22.3096, 3.7183	106.7060, 13.1346
	MEDIAN	27478.800	35801.000	33133.100	18.075	14.608	15.180
	MIN, MAX	125.965, 88340.540	2083.307, 94457.177	125.965, 94457.177	4.553, 793.718	3.902, 108.790	3.902, 793.718
	5%, 95%	125.965, 88340.500	4602.740, 78215.800	3761.070, 78215.800	4.693, 312.882	6.452, 71.021	5.323, 166.288
	BLQ Values Included	0	0	0	3	15	18
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	31964.900, 18097.300	32190.600, 25748.700	32107.100, 22602.700	50.652, 25.096	19.391, 14.936	33.601, 18.909
	SD, SE	25965.0000, 6297.4300	19727.1000, 3663.2200	21951.4000, 3236.5500	81.3493, 14.8523	17.4450, 2.9075	57.9863, 7.1376
	MEDIAN	24744.000	28504.500	26373.800	15.459	14.272	15.058
	MIN, MAX	111.235, 78677.060	5081.697, 70601.838	111.235, 78677.060	7.440, 378.778	5.151, 87.566	5.151, 378.778
	5%, 95%	111.235, 78677.100	6008.340, 67792.100	5081.700, 74000.000	8.949, 201.616	5.557, 54.777	6.764, 164.467
	BLQ Values Included	0	0	0	8	23	31
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	31204.300, 19756.900	31988.700, 25268.500	31706.300, 23126.500	60.480, 28.902	21.117, 16.555	39.009, 21.327
	SD, SE	22290.7000, 5253.9700	20029.7000, 3540.7800	20648.1000, 2920.0800	92.1883, 16.8312	17.1189, 2.8532	65.8755, 8.1087
	MEDIAN	26314.100	28372.100	27628.600	22.896	14.725	16.540
	MIN, MAX	152.674, 89607.000	2637.300, 85014.100	152.674, 89607.000	6.643, 400.319	5.402, 77.098	5.402, 400.319
	5%, 95%	152.674, 89607.000	5159.950, 64690.100	3622.480, 64690.100	7.151, 291.961	6.639, 71.284	6.778, 172.570

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free 3-hydroxycotinine (ng/mg Creatinin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	4.056, 2.684	5.165, 3.661	4.766, 3.274	0.006, NA	0.004, 0.003	0.005, NA
	SD, SE	2.5920, 0.6109	3.8502, 0.6806	3.4639, 0.4899	0.0097, 0.0018	0.0062, 0.0010	0.0080, 0.0010
	MEDIAN	4.045	4.391	4.258	0.002	0.002	0.002
	MIN, MAX	0.040, 8.886	0.119, 14.351	0.040, 14.351	0.000, 0.042	0.001, 0.036	0.000, 0.042
	5%, 95%	0.040, 8.886	0.500, 13.466	0.300, 12.478	0.001, 0.032	0.001, 0.016	0.001, 0.019
	BLQ Values Included	0	0	0	7	16	23
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	4.195, 2.776	5.733, 4.264	5.168, 3.642	0.009, NA	0.004, 0.003	0.006, NA
	SD, SE	2.6525, 0.6252	4.0709, 0.7312	3.6621, 0.5232	0.0172, 0.0031	0.0041, 0.0007	0.0122, 0.0015
	MEDIAN	3.834	4.761	4.126	0.003	0.002	0.002
	MIN, MAX	0.027, 10.012	0.400, 15.297	0.027, 15.297	0.000, 0.079	0.001, 0.019	0.000, 0.079
	5%, 95%	0.027, 10.012	0.693, 14.865	0.400, 12.899	0.001, 0.057	0.001, 0.018	0.001, 0.019
	BLQ Values Included	0	0	0	3	15	18
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	4.141, 2.512	5.557, 4.221	5.034, 3.484	0.005, 0.003	0.004, 0.003	0.004, 0.003
	SD, SE	2.9060, 0.7048	4.0050, 0.7437	3.6689, 0.5410	0.0082, 0.0015	0.0038, 0.0006	0.0062, 0.0008
	MEDIAN	3.299	4.139	3.689	0.002	0.002	0.002
	MIN, MAX	0.019, 9.708	0.770, 15.542	0.019, 15.542	0.001, 0.041	0.001, 0.022	0.001, 0.041
	5%, 95%	0.019, 9.708	0.972, 11.857	0.770, 11.642	0.001, 0.018	0.001, 0.008	0.001, 0.017
	BLQ Values Included	0	0	0	8	23	31
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	4.143, 2.740	5.436, 4.136	4.971, 3.566	0.007, 0.003	0.004, 0.003	0.005, 0.003
	SD, SE	2.6080, 0.6147	3.8060, 0.6728	3.4521, 0.4882	0.0100, 0.0018	0.0039, 0.0007	0.0074, 0.0009
	MEDIAN	3.555	4.286	4.113	0.003	0.003	0.003
	MIN, MAX	0.029, 9.245	0.497, 14.264	0.029, 14.264	0.001, 0.037	0.001, 0.019	0.001, 0.037
	5%, 95%	0.029, 9.245	0.654, 12.984	0.497, 12.705	0.001, 0.033	0.001, 0.017	0.001, 0.019

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free 3-hydroxycotinine (nmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	21.104, 13.962	26.874, 19.047	24.797, 17.032	0.032, NA	0.020, 0.013	0.025, NA
	SD, SE	13.4863, 3.1788	20.0325, 3.5413	18.0226, 2.5488	0.0505, 0.0092	0.0321, 0.0053	0.0415, 0.0051
	MEDIAN	21.044	22.847	22.155	0.010	0.010	0.010
	MIN, MAX	0.208, 46.234	0.619, 74.668	0.208, 74.668	0.000, 0.219	0.005, 0.187	0.000, 0.219
	5%, 95%	0.208, 46.234	2.602, 70.064	1.561, 64.923	0.005, 0.166	0.005, 0.083	0.005, 0.099
	BLQ Values Included	0	0	0	7	16	23
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	21.828, 14.439	29.830, 22.188	26.891, 18.948	0.047, NA	0.020, 0.014	0.032, NA
	SD, SE	13.8009, 3.2529	21.1808, 3.8042	19.0536, 2.7219	0.0898, 0.0164	0.0217, 0.0036	0.0636, 0.0078
	MEDIAN	19.946	24.771	21.468	0.013	0.010	0.010
	MIN, MAX	0.140, 52.092	2.081, 79.590	0.140, 79.590	0.000, 0.411	0.005, 0.099	0.000, 0.411
	5%, 95%	0.140, 52.092	3.606, 77.343	2.081, 67.113	0.005, 0.297	0.005, 0.094	0.005, 0.099
	BLQ Values Included	0	0	0	3	15	18
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	21.545, 13.070	28.915, 21.960	26.191, 18.128	0.026, 0.013	0.018, 0.013	0.022, 0.013
	SD, SE	15.1200, 3.6671	20.8379, 3.8695	19.0893, 2.8146	0.0427, 0.0078	0.0199, 0.0033	0.0323, 0.0040
	MEDIAN	17.165	21.535	19.194	0.010	0.010	0.010
	MIN, MAX	0.099, 50.511	4.006, 80.865	0.099, 80.865	0.005, 0.213	0.005, 0.114	0.005, 0.213
	5%, 95%	0.099, 50.511	5.057, 61.692	4.006, 60.573	0.005, 0.094	0.005, 0.042	0.005, 0.088
	BLQ Values Included	0	0	0	8	23	31
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	21.558, 14.243	28.284, 21.519	25.862, 18.548	0.035, 0.016	0.019, 0.014	0.026, 0.015
	SD, SE	13.5702, 3.1985	19.8026, 3.5006	17.9615, 2.5401	0.0521, 0.0095	0.0203, 0.0034	0.0386, 0.0048
	MEDIAN	18.494	22.298	21.398	0.013	0.013	0.013
	MIN, MAX	0.149, 48.103	2.586, 74.215	0.149, 74.215	0.003, 0.194	0.005, 0.099	0.003, 0.194
	5%, 95%	0.149, 48.103	3.405, 67.557	2.586, 66.106	0.003, 0.170	0.005, 0.088	0.005, 0.099
	BLQ Values Included	0	0	0	0	0	0

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: 3-hydroxycotinine glucuronide (nmol/24hr)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	31	49	25	29	54
	MEAN, GEO MEAN	13658.800, 7347.440	9608.180, 6681.410	11096.200, 6918.750	14.677, NA	4.286, NA	9.097, NA
	SD, SE	14825.2000, 3494.3200	6687.0300, 1201.0300	10472.9000, 1496.1300	23.1053, 4.6211	6.8572, 1.2733	17.1446, 2.3331
	MEDIAN	8980.790	8366.020	8366.020	5.640	1.350	2.082
	MIN, MAX	197.400, 56537.828	218.900, 26230.442	197.400, 56537.828	0.000, 86.504	0.000, 30.003	0.000, 86.504
	5%, 95%	197.400, 56537.800	757.770, 25398.700	757.770, 26230.400	0.000, 72.540	0.000, 16.900	0.000, 52.260
	BLQ Values Included	0	0	0	7	16	23
Week 2	N	18	31	49	27	33	60
	MEAN, GEO MEAN	9769.280, 6028.730	10395.100, 7947.640	10165.200, 7180.450	21.598, NA	6.766, NA	13.441, NA
	SD, SE	8845.0300, 2084.7900	6743.3400, 1211.1400	7498.0900, 1071.1600	41.6044, 8.0068	13.1800, 2.2943	30.2054, 3.8995
	MEDIAN	7733.960	9075.580	8992.600	3.198	1.056	1.533
	MIN, MAX	126.000, 38811.750	540.383, 26263.300	126.000, 38811.750	0.000, 202.270	0.000, 62.122	0.000, 202.270
	5%, 95%	126.000, 38811.800	1494.590, 24231.800	622.537, 24231.800	0.000, 75.525	0.000, 31.536	0.000, 60.436
	BLQ Values Included	0	0	0	3	15	18
Week 3	N	17	28	45	28	34	62
	MEAN, GEO MEAN	12597.300, 6606.370	12135.900, 9285.060	12310.200, 8164.710	13.923, NA	3.513, NA	8.214, NA
	SD, SE	14948.0000, 3625.4200	8852.0800, 1672.8900	11374.8000, 1695.6600	25.7235, 4.8613	6.8512, 1.1750	18.5892, 2.3608
	MEDIAN	8891.740	8279.230	8468.660	3.172	0.000	0.995
	MIN, MAX	160.868, 64170.700	1725.522, 33098.780	160.868, 64170.700	0.000, 88.660	0.000, 26.235	0.000, 88.660
	5%, 95%	160.868, 64170.700	2950.620, 31402.400	1725.520, 31402.400	0.000, 86.250	0.000, 25.331	0.000, 42.273
	BLQ Values Included	0	0	0	8	23	31
Overall*	N	18	32	50	30	35	65
	MEAN, GEO MEAN	12023.200, 7040.190	10289.600, 8058.200	10913.700, 7675.780	16.131, NA	4.542, NA	9.891, NA
	SD, SE	11899.5000, 2804.7400	6756.9200, 1194.4700	8872.2500, 1254.7300	26.2059, 4.7845	7.0690, 1.1949	19.2777, 2.3911
	MEDIAN	8821.500	9018.320	9018.320	4.403	1.455	2.395
	MIN, MAX	161.423, 49042.900	828.268, 27011.000	161.423, 49042.900	0.000, 104.787	0.000, 28.585	0.000, 104.787
	5%, 95%	161.423, 49042.900	1717.540, 23927.100	828.268, 27011.000	0.000, 87.582	0.000, 23.501	0.000, 49.847

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 26 of 7)

Biomarker: 3-hydroxycotinine glucuronide (nmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	31	49	25	29	54
	MEAN, GEO MEAN	9.316, 5.558	8.742, 5.873	8.953, 5.755	0.009, NA	0.004, NA	0.006, NA
	SD, SE	8.9395, 2.1071	6.9972, 1.2567	7.6799, 1.0971	0.0145, 0.0029	0.0070, 0.0013	0.0113, 0.0015
	MEDIAN	7.365	6.599	6.754	0.002	0.001	0.002
	MIN, MAX	0.186, 37.904	0.182, 24.795	0.182, 37.904	0.000, 0.053	0.000, 0.034	0.000, 0.053
	5%, 95%	0.186, 37.904	0.724, 24.215	0.365, 24.215	0.000, 0.051	0.000, 0.015	0.000, 0.034
	BLQ Values Included	0	0	0	7	16	23
Week 2	N	18	31	49	27	33	60
	MEAN, GEO MEAN	7.764, 4.431	8.681, 6.311	8.344, 5.542	0.013, NA	0.006, NA	0.009, NA
	SD, SE	8.8779, 2.0925	7.1363, 1.2817	7.7423, 1.1060	0.0244, 0.0047	0.0116, 0.0020	0.0187, 0.0024
	MEDIAN	4.949	6.791	5.726	0.002	0.001	0.001
	MIN, MAX	0.141, 37.773	0.539, 31.266	0.141, 37.773	0.000, 0.105	0.000, 0.053	0.000, 0.105
	5%, 95%	0.141, 37.773	1.171, 24.592	0.539, 24.592	0.000, 0.072	0.000, 0.041	0.000, 0.047
	BLQ Values Included	0	0	0	3	15	18
Week 3	N	17	28	45	28	34	62
	MEAN, GEO MEAN	9.048, 4.767	10.684, 7.829	10.066, 6.491	0.007, NA	0.003, NA	0.005, NA
	SD, SE	10.5051, 2.5479	9.3656, 1.7699	9.7261, 1.4499	0.0127, 0.0024	0.0070, 0.0012	0.0101, 0.0013
	MEDIAN	6.526	7.318	6.677	0.002	0.000	0.001
	MIN, MAX	0.141, 41.198	1.718, 40.332	0.141, 41.198	0.000, 0.050	0.000, 0.034	0.000, 0.050
	5%, 95%	0.141, 41.198	1.968, 30.778	1.718, 30.778	0.000, 0.040	0.000, 0.018	0.000, 0.030
	BLQ Values Included	0	0	0	8	23	31
Overall*	N	18	32	50	30	35	65
	MEAN, GEO MEAN	8.691, 5.073	9.174, 6.798	9.000, 6.118	0.009, NA	0.004, NA	0.006, NA
	SD, SE	9.1846, 2.1648	7.2907, 1.2888	7.9341, 1.1220	0.0147, 0.0027	0.0072, 0.0012	0.0115, 0.0014
	MEDIAN	5.838	6.767	6.640	0.002	0.001	0.002
	MIN, MAX	0.156, 38.958	0.813, 30.859	0.156, 38.958	0.000, 0.052	0.000, 0.036	0.000, 0.052
	5%, 95%	0.156, 38.958	1.351, 26.074	0.813, 26.074	0.000, 0.049	0.000, 0.021	0.000, 0.036

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 27 of 7)

Biomarker: 3-hydroxycotinine glucuronide (nmol/L)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	31	49	25	29	54
	MEAN, GEO MEAN	8694.8, 4489.1	5851.2, 3777.8	6895.8, 4024.9	9.6, NA	2.7, NA	5.9, NA
	SD, SE	11055.20, 2605.73	4628.53, 831.31	7654.61, 1093.52	19.76, 3.95	4.60, 0.85	14.15, 1.93
	MEDIAN	5531.3	4515.7	5136.9	3.6	1.0	1.9
	MIN, MAX	140.0, 48117.3	79.6, 16292.2	79.6, 48117.3	0.0, 98.3	0.0, 21.9	0.0, 98.3
	5%, 95%	140.0, 48117.3	649.9, 14940.4	649.9, 16292.2	0.0, 26.0	0.0, 9.9	0.0, 21.9
	BLQ Values Included	0	0	0	7	16	23
Week 2	N	18	31	49	27	33	60
	MEAN, GEO MEAN	6920.4, 4258.9	6590.7, 4879.1	6711.8, 4641.4	15.0, NA	3.5, NA	8.7, NA
	SD, SE	5859.62, 1381.13	4718.06, 847.39	5108.69, 729.81	35.65, 6.86	6.91, 1.20	24.88, 3.21
	MEDIAN	5673.1	5492.3	5545.9	1.6	0.5	1.6
	MIN, MAX	140.0, 23215.8	296.1, 18931.1	140.0, 23215.8	0.0, 179.0	0.0, 34.9	0.0, 179.0
	5%, 95%	140.0, 23215.8	1061.9, 15749.0	596.3, 15749.0	0.0, 62.4	0.0, 15.6	0.0, 36.5
	BLQ Values Included	0	0	0	3	15	18
Week 3	N	17	28	45	28	34	62
	MEAN, GEO MEAN	7528.7, 3907.3	7528.8, 5371.4	7528.7, 4762.9	7.6, NA	1.9, NA	4.5, NA
	SD, SE	8771.50, 2127.40	7767.25, 1467.87	8062.18, 1201.84	14.35, 2.71	3.45, 0.59	10.28, 1.31
	MEDIAN	5225.9	4873.4	5225.9	2.1	0.0	0.5
	MIN, MAX	153.5, 29731.5	927.7, 40612.0	153.5, 40612.0	0.0, 68.2	0.0, 14.6	0.0, 68.2
	5%, 95%	153.5, 29731.5	1603.6, 16665.7	927.7, 29168.5	0.0, 27.6	0.0, 9.9	0.0, 24.5
	BLQ Values Included	0	0	0	8	23	31
Overall*	N	18	32	50	30	35	65
	MEAN, GEO MEAN	7766.0, 4760.1	6416.1, 4776.7	6902.1, 4770.7	10.7, NA	2.6, NA	6.3, NA
	SD, SE	6698.46, 1578.84	4868.46, 860.63	5566.90, 787.28	19.45, 3.55	3.97, 0.67	14.01, 1.74
	MEDIAN	6527.5	4925.5	5704.9	4.0	0.9	1.6
	MIN, MAX	144.5, 25999.9	434.5, 22446.3	144.5, 25999.9	0.0, 83.3	0.0, 17.4	0.0, 83.3
	5%, 95%	144.5, 25999.9	855.9, 14963.3	640.7, 19989.6	0.0, 71.1	0.0, 13.2	0.0, 22.2

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 28 of ?)

Biomarker: Total NNAL (pg/24hr)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	17	32	49	30	36	66
	MEAN, GEO MEAN	803983.000, 509040.000	890921.000, 630564.000	860759.000, 585425.000	17773.200, 11018.600	11639.900, 10687.400	14427.700, 10836.700
	SD, SE	609148.0000, 147740.0000	623306.0000, 110186.0000	613472.0000, 87638.9000	32167.7000, 5872.9800	4679.1900, 779.8640	21975.5000, 2704.9900
	MEDIAN	529126.000	801427.000	785030.000	8940.000	10950.000	9870.000
	MIN, MAX	8460.000, 2084332.500	34650.000, 2307613.000	8460.000, 2307613.000	3180.000, 181986.000	3420.000, 20100.000	3180.000, 181986.000
	5%, 95%	8460.000, 2084330.000	37125.000, 2245880.000	37125.000, 2084330.000	3900.000, 41624.000	4800.000, 19500.000	4680.000, 21000.000
	BLQ Values Included	1	0	1	24	35	59
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	780889.000, 484578.000	992757.000, 730892.000	914458.000, 627899.000	13735.500, 11563.300	14986.400, 13043.200	14417.800, 12348.400
	SD, SE	625370.0000, 151675.0000	753693.0000, 139957.0000	709365.0000, 104590.0000	10652.4000, 1944.8500	10205.6000, 1700.9300	10349.1000, 1273.8800
	MEDIAN	540730.000	928092.000	783064.000	10740.000	12240.000	12000.000
	MIN, MAX	6288.000, 2075948.000	56730.000, 4046406.000	6288.000, 4046406.000	4500.000, 61490.000	5940.000, 53066.000	4500.000, 61490.000
	5%, 95%	6288.000, 2075950.000	97520.000, 1962480.000	97520.000, 1964160.000	4500.000, 28208.000	6408.000, 50799.000	6408.000, 28440.000
	BLQ Values Included	1	0	1	26	33	59
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	803960.000, 518626.000	914026.000, 677521.000	874402.000, 615372.000	15754.400, 11765.800	13313.100, 12169.200	14422.800, 11984.200
	SD, SE	602619.0000, 142039.0000	592843.0000, 104801.0000	592616.0000, 83808.5000	17937.4000, 3274.9000	6265.6100, 1044.2700	12891.4000, 1586.8300
	MEDIAN	619904.000	855140.000	839770.000	9780.000	12060.000	11130.000
	MIN, MAX	7374.000, 2080140.000	46927.500, 2468210.000	7374.000, 2468210.000	3840.000, 97218.000	6400.000, 33874.500	3840.000, 97218.000
	5%, 95%	7374.000, 2080140.000	66085.000, 2135050.000	66085.000, 2080140.000	4590.000, 51557.000	6450.000, 30583.000	6400.000, 30583.000

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 29 of ?)

Biomarker: Total NNAL (pmol/24hr)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	17	32	49	30	36	66
	MEAN, GEO MEAN	3843.040, 2433.210	4258.600, 3014.090	4114.430, 2798.330	84.956, 52.669	55.639, 51.086	68.965, 51.799
	SD, SE	2911.7300, 706.1980	2979.4000, 526.6890	2932.4000, 418.9140	153.7610, 28.0729	22.3664, 3.7277	105.0430, 12.9299
	MEDIAN	2529.220	3830.820	3752.440	42.733	52.341	47.179
	MIN, MAX	40.439, 9963.109	165.627, 11030.390	40.439, 11030.390	15.200, 869.893	16.348, 96.078	15.200, 869.893
	5%, 95%	40.439, 9963.110	177.458, 10735.300	177.458, 9963.110	18.642, 198.963	22.944, 93.210	22.370, 100.380
	BLQ Values Included	1	0	1	24	35	59
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	3732.650, 2316.290	4745.380, 3493.660	4371.110, 3001.360	65.656, 55.272	71.635, 62.347	68.917, 59.025
	SD, SE	2989.2700, 725.0040	3602.6500, 668.9960	3390.7700, 499.9410	50.9184, 9.2964	48.7827, 8.1304	49.4686, 6.0892
	MEDIAN	2584.690	4436.280	3743.050	51.337	58.507	57.360
	MIN, MAX	30.057, 9923.031	271.169, 19341.821	30.057, 19341.821	21.510, 293.922	28.393, 253.655	21.510, 293.922
	5%, 95%	30.057, 9923.030	466.146, 9380.650	466.146, 9388.690	21.510, 134.834	30.630, 242.819	30.630, 135.943
	BLQ Values Included	1	0	1	26	33	59
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	3842.930, 2479.030	4369.040, 3238.550	4179.640, 2941.480	75.306, 56.241	63.637, 58.169	68.941, 57.285
	SD, SE	2880.5200, 678.9450	2833.7800, 500.9470	2832.7000, 400.6040	85.7407, 15.6540	29.9496, 4.9916	61.6210, 7.5850
	MEDIAN	2963.140	4087.570	4014.100	46.749	57.647	53.202
	MIN, MAX	35.248, 9943.070	224.314, 11798.000	35.248, 11798.000	18.355, 464.702	30.592, 161.920	18.355, 464.702
	5%, 95%	35.248, 9943.070	315.887, 10205.500	315.887, 9943.070	21.940, 246.443	30.831, 146.187	30.592, 146.187

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total NNAL (pg/mg Creatinin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	17	32	49	30	36	66
	MEAN, GEO MEAN	632.351, 388.963	794.208, 549.931	738.054, 487.673	11.176, 6.201	10.025, 9.154	10.548, 7.669
	SD, SE	604.3900, 146.5860	576.5670, 101.9240	585.2480, 83.6069	23.9321, 4.3694	3.9996, 0.6666	16.2628, 2.0018
	MEDIAN	339.746	629.249	625.442	5.013	9.547	9.003
	MIN, MAX	7.958, 2575.145	18.519, 2476.718	7.958, 2575.145	1.932, 134.956	2.285, 18.634	1.932, 134.956
	5%, 95%	7.958, 2575.150	30.892, 2010.240	30.892, 2010.240	2.103, 25.707	3.883, 17.699	2.683, 17.699
	BLQ Values Included	1	0	1	24	35	59
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	533.334, 349.698	832.490, 623.362	721.933, 503.456	7.775, 6.330	13.976, 11.516	11.157, 8.773
	SD, SE	387.2530, 93.9228	567.0180, 105.2930	524.1050, 77.2750	6.1746, 1.1273	10.4619, 1.7437	9.2533, 1.1390
	MEDIAN	381.623	634.698	580.019	6.049	10.657	8.596
	MIN, MAX	5.525, 1261.017	56.481, 2275.640	5.525, 2275.640	2.158, 34.375	3.259, 53.767	2.158, 53.767
	5%, 95%	5.525, 1261.020	65.031, 2024.780	65.031, 2004.780	2.413, 15.074	3.793, 41.549	2.923, 30.000
	BLQ Values Included	1	0	1	26	33	59
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	581.550, 377.045	808.453, 587.104	726.768, 500.586	9.476, 6.637	12.001, 10.673	10.853, 8.600
	SD, SE	470.7100, 110.9470	554.2550, 97.9794	532.2830, 75.2762	12.6956, 2.3179	6.1929, 1.0322	9.7040, 1.1945
	MEDIAN	389.237	654.457	617.106	5.327	10.666	8.560
	MIN, MAX	6.742, 1877.500	41.775, 2250.750	6.742, 2250.750	2.131, 70.371	3.634, 30.459	2.131, 70.371
	5%, 95%	6.742, 1877.500	43.687, 2007.510	43.687, 1877.500	2.364, 30.041	4.739, 27.562	3.508, 27.562

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234' for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 31 of ?)

Biomarker: Total NNAL (pmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	17	32	49	30	36	66
	MEAN, GEO MEAN	3.023, 1.859	3.796, 2.629	3.528, 2.331	0.053, 0.030	0.048, 0.044	0.050, 0.037
	SD, SE	2.8890, 0.7007	2.7560, 0.4872	2.7975, 0.3996	0.1144, 0.0209	0.0191, 0.0032	0.0777, 0.0096
	MEDIAN	1.624	3.008	2.990	0.024	0.046	0.043
	MIN, MAX	0.038, 12.309	0.089, 11.839	0.038, 12.309	0.009, 0.645	0.011, 0.089	0.009, 0.645
	5%, 95%	0.038, 12.309	0.148, 9.609	0.148, 9.609	0.010, 0.123	0.019, 0.085	0.013, 0.085
	BLQ Values Included	1	0	1	24	35	59
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	2.549, 1.670	3.979, 2.980	3.451, 2.406	0.037, 0.030	0.067, 0.055	0.053, 0.042
	SD, SE	1.8512, 0.4490	2.7104, 0.5033	2.5053, 0.3694	0.0295, 0.0054	0.0500, 0.0083	0.0442, 0.0054
	MEDIAN	1.824	3.034	2.773	0.029	0.051	0.041
	MIN, MAX	0.026, 6.028	0.270, 10.878	0.026, 10.878	0.010, 0.164	0.016, 0.257	0.010, 0.257
	5%, 95%	0.026, 6.028	0.311, 9.678	0.311, 9.583	0.012, 0.072	0.018, 0.199	0.014, 0.143
	BLQ Values Included	1	0	1	26	33	59
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	2.780, 1.802	3.865, 2.807	3.474, 2.393	0.046, 0.032	0.058, 0.051	0.052, 0.041
	SD, SE	2.2501, 0.5304	2.6493, 0.4683	2.5443, 0.3598	0.0608, 0.0111	0.0295, 0.0049	0.0464, 0.0057
	MEDIAN	1.861	3.129	2.950	0.026	0.052	0.042
	MIN, MAX	0.032, 8.975	0.200, 10.759	0.032, 10.759	0.010, 0.337	0.018, 0.146	0.010, 0.337
	5%, 95%	0.032, 8.975	0.209, 9.596	0.209, 8.975	0.011, 0.144	0.023, 0.132	0.017, 0.132

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 32 of 7)

Biomarker: Free NNAL (pg/24hr)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	191275.000, 138941.000	281920.000, 211579.000	249288.000, 181853.000	10411.800, 9179.580	12439.400, 11029.500	11517.800, 10146.400
	SD, SE	118708.0000, 27979.8000	201341.0000, 35592.4000	180187.0000, 25482.3000	5411.7100, 988.0390	6462.2300, 1077.0400	6048.7800, 744.5530
	MEDIAN	192779.000	234059.000	224364.000	8190.000	10950.000	9240.000
	MIN, MAX	8460.000, 409840.000	16500.000, 852355.000	8460.000, 852355.000	3180.000, 22800.000	3420.000, 30796.800	3180.000, 30796.800
	5%, 95%	8460.000, 409840.000	23940.000, 671265.000	23940.000, 649460.000	3900.000, 20100.000	4800.000, 27840.000	4800.000, 22800.000
	BLQ Values Included	1	1	2	29	33	62
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	229255.000, 150668.000	307184.000, 256566.000	278384.000, 210748.000	15485.700, 12411.500	12918.400, 12046.400	14085.400, 12211.000
	SD, SE	184405.0000, 44724.9000	164685.0000, 30581.3000	174392.0000, 25712.7000	12690.8000, 2317.0200	4911.6600, 818.6110	9300.8400, 1144.8500
	MEDIAN	162848.000	286356.000	241481.000	11400.000	12240.000	12090.000
	MIN, MAX	6288.000, 573980.000	45936.000, 781704.000	6288.000, 781704.000	4500.000, 57240.000	5640.000, 28440.000	4500.000, 57240.000
	5%, 95%	6288.000, 573980.000	52452.000, 535470.000	52440.000, 558700.000	4500.000, 52910.000	5940.000, 20100.000	5940.000, 28440.000
	BLQ Values Included	1	0	1	27	35	62
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	210261.000, 149954.000	287127.000, 234338.000	259455.000, 199547.000	12948.800, 11411.300	12678.900, 11739.600	12801.600, 11589.200
	SD, SE	140302.0000, 33069.5000	166377.0000, 29411.6000	160409.0000, 22685.3000	7000.2100, 1278.0600	5245.6000, 874.2670	6057.8600, 745.6710
	MEDIAN	185851.000	262597.000	239327.000	10033.500	12060.000	11217.000
	MIN, MAX	7374.000, 426577.000	34476.000, 589956.000	7374.000, 589956.000	3840.000, 32310.000	5910.000, 28140.000	3840.000, 32310.000
	5%, 95%	7374.000, 426577.000	53922.000, 588893.000	47776.000, 584079.000	5280.000, 29095.000	6450.000, 24998.400	6450.000, 24998.400

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., <1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 33 of ?)

Biomarker: Free NNAL (pmol/24hr)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	914.293, 664.139	1347.580, 1011.350	1191.600, 869.259	49.768, 43.878	59.461, 52.721	55.055, 48.500
	SD, SE	567.4250, 133.7430	962.4100, 170.1320	861.2930, 121.8050	25.8680, 4.7228	30.8894, 5.1482	28.9132, 3.5590
	MEDIAN	921.484	1118.800	1072.460	39.148	52.341	44.168
	MIN, MAX	40.439, 1959.035	78.870, 4074.257	40.439, 4074.257	15.200, 108.984	16.348, 147.209	15.200, 147.209
	5%, 95%	40.439, 1959.040	114.433, 3208.650	114.433, 3104.420	18.642, 96.078	22.944, 133.075	22.944, 108.984
	BLQ Values Included	1	1	2	29	33	62
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	1095.840, 720.195	1468.340, 1226.390	1330.680, 1007.380	74.022, 59.327	61.750, 57.582	67.328, 58.369
	SD, SE	881.4580, 213.7850	787.1950, 146.1780	833.5930, 122.9070	60.6622, 11.0754	23.4777, 3.9130	44.4580, 5.4724
	MEDIAN	778.413	1368.780	1154.280	54.492	58.507	57.790
	MIN, MAX	30.057, 2743.624	219.574, 3736.545	30.057, 3736.545	21.510, 273.607	26.959, 135.943	21.510, 273.607
	5%, 95%	30.057, 2743.620	250.721, 2559.550	250.663, 2670.580	21.510, 252.910	28.393, 96.078	28.393, 135.943
	BLQ Values Included	1	0	1	27	35	62
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1005.050, 716.780	1372.470, 1120.140	1240.200, 953.832	61.895, 54.546	60.606, 56.115	61.192, 55.397
	SD, SE	670.6430, 158.0720	795.2830, 140.5880	766.7570, 108.4360	33.4610, 6.1091	25.0740, 4.1790	28.9566, 3.5643
	MEDIAN	888.366	1255.220	1143.980	47.961	57.647	53.618
	MIN, MAX	35.248, 2039.040	164.796, 2819.990	35.248, 2819.990	18.355, 154.442	28.250, 134.509	18.355, 154.442
	5%, 95%	35.248, 2039.040	257.747, 2814.910	228.369, 2791.900	25.239, 139.074	30.831, 119.493	30.831, 119.493

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234' for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 34 of 7)

Biomarker: Free NNAL (pg/mg Creatinin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	160.048, 105.095	252.415, 184.524	219.163, 150.676	5.942, 5.166	10.668, 9.447	8.520, 7.180
	SD, SE	171.2220, 40.3573	181.5310, 32.0904	181.7280, 25.7002	3.3379, 0.6094	5.3826, 0.8971	5.1180, 0.6300
	MEDIAN	105.373	208.248	178.751	4.491	9.547	8.222
	MIN, MAX	7.958, 767.052	12.795, 813.359	7.958, 813.359	1.932, 14.815	2.285, 29.814	1.932, 29.814
	5%, 95%	7.958, 767.052	13.730, 612.755	13.730, 612.755	2.683, 11.788	3.436, 20.782	2.911, 17.143
	BLQ Values Included	1	1	2	29	33	62
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	153.041, 108.730	270.188, 218.820	226.894, 168.981	8.665, 6.794	12.110, 10.636	10.544, 8.676
	SD, SE	106.2860, 23.7781	171.0360, 31.7606	159.6470, 23.5386	6.9510, 1.2691	6.4161, 1.0694	6.8346, 0.8413
	MEDIAN	109.091	225.402	194.555	6.367	10.657	9.325
	MIN, MAX	5.525, 368.503	47.240, 724.324	5.525, 724.324	2.158, 30.264	3.259, 30.000	2.158, 30.264
	5%, 95%	5.525, 368.503	52.222, 553.597	47.240, 547.012	2.413, 29.578	3.795, 29.412	2.923, 29.412
	BLQ Values Included	1	0	1	27	35	62
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	155.884, 110.331	260.848, 202.542	223.061, 162.757	7.304, 6.332	11.389, 10.300	9.532, 8.256
	SD, SE	125.4040, 29.5580	177.8690, 31.4432	167.5170, 23.6904	4.0261, 0.7351	5.0339, 0.8390	5.0078, 0.6164
	MEDIAN	121.636	207.009	185.127	5.790	10.666	8.678
	MIN, MAX	6.742, 522.399	32.976, 768.842	6.742, 768.842	2.364, 17.426	3.348, 23.043	2.364, 23.043
	5%, 95%	6.742, 522.399	34.373, 612.755	34.373, 535.268	2.693, 16.420	4.532, 21.741	3.185, 19.673

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 35 of ?)

Biomarker: Free NNAL (pmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	0.765, 0.502	1.207, 0.882	1.048, 0.720	0.028, 0.025	0.051, 0.045	0.041, 0.034
	SD, SE	0.8185, 0.1929	0.8678, 0.1534	0.8687, 0.1229	0.0160, 0.0029	0.0258, 0.0043	0.0245, 0.0030
	MEDIAN	0.504	0.996	0.855	0.022	0.046	0.039
	MIN, MAX	0.038, 3.667	0.061, 3.888	0.038, 3.888	0.009, 0.071	0.011, 0.143	0.009, 0.143
	5%, 95%	0.038, 3.667	0.066, 2.929	0.066, 2.929	0.013, 0.056	0.016, 0.099	0.014, 0.082
	BLQ Values Included	1	1	2	29	33	62
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	0.731, 0.519	1.291, 1.046	1.085, 0.807	0.041, 0.032	0.058, 0.051	0.050, 0.041
	SD, SE	0.5080, 0.1232	0.8175, 0.1518	0.7631, 0.1125	0.0332, 0.0061	0.0306, 0.0051	0.0326, 0.0040
	MEDIAN	0.521	1.077	0.930	0.031	0.051	0.045
	MIN, MAX	0.026, 1.761	0.226, 3.462	0.026, 3.462	0.010, 0.145	0.016, 0.143	0.010, 0.145
	5%, 95%	0.026, 1.761	0.250, 2.646	0.226, 2.615	0.012, 0.141	0.018, 0.141	0.014, 0.141
	BLQ Values Included	1	0	1	27	35	62
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	0.745, 0.527	1.247, 0.968	1.066, 0.778	0.035, 0.030	0.055, 0.049	0.046, 0.040
	SD, SE	0.5996, 0.1413	0.8503, 0.1503	0.8008, 0.1132	0.0193, 0.0035	0.0240, 0.0040	0.0239, 0.0029
	MEDIAN	0.582	0.990	0.885	0.028	0.052	0.042
	MIN, MAX	0.032, 2.498	0.158, 3.675	0.032, 3.675	0.011, 0.084	0.016, 0.110	0.011, 0.110
	5%, 95%	0.032, 2.498	0.164, 2.929	0.164, 2.559	0.013, 0.079	0.022, 0.104	0.015, 0.094

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 36 of ?)

Biomarker: NNAL-Glucuronide (pmol/L)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	17	32	49	29	33	62
	MEAN, GEO MEAN	1950.1, NA	1856.6, 1069.4	1889.1, NA	37.9, NA	0.1, NA	17.8, NA
	SD, SE	2050.37, 497.29	1691.41, 299.00	1803.06, 257.58	162.11, 30.10	0.84, 0.15	111.46, 14.16
	MEDIAN	1543.0	1631.9	1564.5	0.0	0.0	0.0
	MIN, MAX	0.0, 7358.3	24.4, 7462.5	0.0, 7462.5	0.0, 859.0	0.0, 4.8	0.0, 859.0
	5%, 95%	0.0, 7358.3	35.9, 5458.8	35.9, 5782.8	0.0, 197.4	0.0, 0.0	0.0, 13.4
	BLQ Values Included	1	1	2	29	33	62
Week 3	N	17	29	46	28	36	64
	MEAN, GEO MEAN	1457.1, NA	2115.3, 1152.9	1872.0, NA	2.0, NA	5.1, NA	3.7, NA
	SD, SE	1136.78, 275.71	2223.97, 412.98	1907.93, 281.31	6.52, 1.23	19.24, 3.21	15.05, 1.88
	MEDIAN	1234.2	1443.6	1352.5	0.0	0.0	0.0
	MIN, MAX	0.0, 4514.7	11.0, 9536.6	0.0, 9536.6	0.0, 31.5	0.0, 99.9	0.0, 99.9
	5%, 95%	0.0, 4514.7	35.4, 7004.1	35.4, 5911.9	0.0, 12.4	0.0, 55.9	0.0, 28.2
	BLQ Values Included	1	0	1	27	35	62
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1744.6, NA	1924.2, 1135.3	1859.5, NA	19.2, NA	2.6, NA	10.2, NA
	SD, SE	1455.58, 343.08	1730.55, 305.92	1623.98, 229.67	80.23, 14.65	9.62, 1.60	54.69, 6.73
	MEDIAN	1277.7	1626.1	1521.7	0.0	0.0	0.0
	MIN, MAX	0.0, 4879.9	23.5, 5778.3	0.0, 5778.3	0.0, 429.5	0.0, 50.0	0.0, 429.5
	5%, 95%	0.0, 4879.9	29.9, 5681.3	29.9, 5668.4	0.0, 114.5	0.0, 28.0	0.0, 28.0

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: NNAL-Glucuronide (pmol/24hr)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	17	32	49	29	33	62
	MEAN, GEO MEAN	2904.960, NA	2911.040, 1872.340	2908.930, NA	38.243, NA	0.143, NA	17.964, NA
	SD, SE	2489.6700, 603.8330	2191.8600, 387.4700	2273.5200, 324.7890	158.0830, 29.3553	0.8189, 0.1425	108.8050, 13.8183
	MEDIAN	1833.190	2516.880	2416.280	0.000	0.000	0.000
	MIN, MAX	0.000, 8646.003	51.240, 8788.668	0.000, 8788.668	0.000, 841.820	0.000, 4.704	0.000, 841.820
	5%, 95%	0.000, 8646.000	98.725, 7630.840	98.725, 7630.840	0.000, 173.712	0.000, 0.000	0.000, 21.417
	BLQ Values Included	1	1	2	29	33	62
Week 3	N	17	29	46	28	36	64
	MEAN, GEO MEAN	2636.820, NA	3277.050, 1978.540	3040.440, NA	3.352, NA	9.883, NA	7.025, NA
	SD, SE	2140.5700, 519.1640	3205.0800, 595.1680	2849.3100, 420.1080	10.3068, 1.9478	38.3329, 6.3888	29.5386, 3.6923
	MEDIAN	1703.200	2646.910	2468.520	0.000	0.000	0.000
	MIN, MAX	0.000, 7252.530	20.460, 17356.612	0.000, 17356.612	0.000, 40.950	0.000, 168.831	0.000, 168.831
	5%, 95%	0.000, 7252.530	65.136, 6821.100	65.136, 6821.100	0.000, 36.120	0.000, 160.433	0.000, 36.120
	BLQ Values Included	1	0	1	27	35	62
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	2839.650, NA	2996.590, 1953.510	2940.090, NA	20.049, NA	5.007, NA	11.844, NA
	SD, SE	2316.2800, 545.9520	2267.1100, 400.7720	2262.4900, 319.9650	78.3074, 14.2969	19.1532, 3.1922	54.6839, 6.7311
	MEDIAN	2120.440	2644.190	2635.940	0.000	0.000	0.000
	MIN, MAX	0.000, 7949.270	58.188, 10073.400	0.000, 10073.400	0.000, 420.910	0.000, 84.416	0.000, 420.910
	5%, 95%	0.000, 7949.270	59.593, 7804.880	59.593, 7804.880	0.000, 107.331	0.000, 80.217	0.000, 80.217

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: NNAL-Glucuronide (pmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	17	32	49	29	33	62
	MEAN, GEO MEAN	2.232, NA	2.590, 1.632	2.466, NA	0.027, NA	0.000, NA	0.013, NA
	SD, SE	2.1168, 0.5134	2.0000, 0.3535	2.0265, 0.2895	0.1166, 0.0217	0.0005, 0.0001	0.0801, 0.0102
	MEDIAN	1.190	2.237	2.190	0.000	0.000	0.000
	MIN, MAX	0.000, 8.643	0.027, 7.951	0.000, 8.643	0.000, 0.624	0.000, 0.003	0.000, 0.624
	5%, 95%	0.000, 8.643	0.032, 7.656	0.032, 7.656	0.000, 0.107	0.000, 0.000	0.000, 0.009
	BLQ Values Included	1	1	2	29	33	62
Week 3	N	17	29	46	28	36	64
	MEAN, GEO MEAN	1.818, NA	2.688, 1.686	2.366, NA	0.002, NA	0.009, NA	0.006, NA
	SD, SE	1.3733, 0.3331	2.1935, 0.4073	1.9608, 0.2891	0.0056, 0.0011	0.0354, 0.0059	0.0269, 0.0034
	MEDIAN	1.355	1.939	1.823	0.000	0.000	0.000
	MIN, MAX	0.000, 4.312	0.020, 9.761	0.000, 9.761	0.000, 0.023	0.000, 0.171	0.000, 0.171
	5%, 95%	0.000, 4.312	0.043, 6.968	0.043, 6.216	0.000, 0.019	0.000, 0.131	0.000, 0.019
	BLQ Values Included	1	0	1	27	35	62
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	2.037, NA	2.618, 1.692	2.409, NA	0.014, NA	0.005, NA	0.009, NA
	SD, SE	1.6980, 0.4002	1.9471, 0.3442	1.8649, 0.2637	0.0576, 0.0105	0.0178, 0.0030	0.0409, 0.0050
	MEDIAN	1.169	2.014	1.986	0.000	0.000	0.000
	MIN, MAX	0.000, 6.478	0.035, 7.312	0.000, 7.312	0.000, 0.312	0.000, 0.086	0.000, 0.312
	5%, 95%	0.000, 6.478	0.051, 7.084	0.051, 6.478	0.000, 0.065	0.000, 0.066	0.000, 0.065

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Nicotine (nmol/24hr)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	1	2	3
	MEAN, GEO MEAN	18044.400, 14878.500	8635.730, 8049.120	13340.100, 10943.400	38.100, 38.100	27.991, 24.918	31.361, 28.707
	SD, SE	10825.2000, 6249.9100	4082.2800, 2356.9000	8949.6800, 3653.6900	NA, NA	18.0326, 12.7510	14.0233, 8.0963
	MEDIAN	23200.400	7159.230	10205.000	38.100	27.991	38.100
	MIN, MAX	5605.104, 25327.788	5497.128, 13250.825	5497.128, 25327.788	38.100, 38.100	15.240, 40.742	15.240, 40.742
	5%, 95%	5605.100, 25327.800	5497.130, 13250.800	5497.130, 25327.800	NA, NA	15.240, 40.742	15.240, 40.742
Week 2	BLQ Values Included	0	0	0	1	2	3
	N	3	3	6	2	3	5
	MEAN, GEO MEAN	13631.100, 12261.200	11106.900, 10275.600	12369.000, 11224.600	35.878, 35.865	43.690, 43.268	40.565, 40.139
	SD, SE	6848.8600, 3954.1900	5507.4000, 3179.7000	5727.7200, 2338.3300	1.3470, 0.9525	7.4446, 4.2981	6.8172, 3.0487
	MEDIAN	14725.700	9159.570	11942.600	35.878	43.180	36.830
	MIN, MAX	6300.791, 19866.660	6837.732, 17323.410	6300.791, 19866.660	34.925, 36.830	36.513, 51.376	34.925, 51.376
Week 3	5%, 95%	6300.790, 19866.700	6837.730, 17323.400	6300.790, 19866.700	34.925, 36.830	36.513, 51.376	34.925, 51.376
	BLQ Values Included	0	0	0	2	2	4
	N	2	3	5	4	3	7
	MEAN, GEO MEAN	8440.240, 6209.580	10011.500, 9589.060	9383.020, 8059.170	30.715, 30.052	26.839, 24.948	29.054, 27.748
	SD, SE	8084.4000, 5716.5300	3639.1700, 2101.0800	4868.4500, 2177.2400	7.2646, 3.6323	12.5835, 7.2651	9.1357, 3.4530
	MEDIAN	8440.240	9143.680	9143.680	31.522	23.876	26.213
Overall*	MIN, MAX	2723.706, 14156.770	6884.745, 14006.175	2723.706, 14156.770	22.860, 36.957	16.002, 40.640	16.002, 40.640
	5%, 95%	2723.710, 14156.800	6884.750, 14006.200	2723.710, 14156.800	22.860, 36.957	16.002, 40.640	16.002, 40.640
	BLQ Values Included	0	0	0	4	3	7
	N	3	3	6	4	3	7
	MEAN, GEO MEAN	14541.100, 12230.500	9918.040, 9370.860	12229.600, 10705.600	30.641, 29.992	33.455, 33.106	31.847, 31.289
	SD, SE	8379.8200, 4838.0900	4289.5900, 2476.6000	6469.9800, 2641.3600	7.1809, 3.5904	5.8798, 3.3947	6.2904, 2.3775
Overall*	MEDIAN	18963.100	7734.520	11297.300	31.437	33.528	33.528
	MIN, MAX	4876.530, 19783.700	7159.510, 14860.100	4876.530, 19783.700	22.860, 36.830	27.539, 39.298	22.860, 39.298
	5%, 95%	4876.530, 19783.700	7159.510, 14860.100	4876.530, 19783.700	22.860, 36.830	27.539, 39.298	22.860, 39.298

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Nicotine (ug/24hr)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	1	2	3
	MEAN, GEO MEAN	2926.810, 2413.290	1400.720, 1305.570	2163.760, 1775.030	6.180, 6.180	4.540, 4.042	5.087, 4.656
	SD, SE	1755.8400, 1013.7400	662.1460, 382.2900	1451.6400, 592.6290	NA, NA	2.9246, 2.0680	2.2745, 1.3132
	MEDIAN	3763.110	1161.230	1655.260	6.180	4.540	6.180
	MIN, MAX	909.148, 4108.167	891.634, 2149.284	891.634, 4108.167	6.180, 6.180	2.472, 6.608	2.472, 6.608
	5%, 95%	909.148, 4108.170	891.634, 2149.280	891.634, 4108.170	NA, NA	2.472, 6.608	2.472, 6.608
	BLQ Values Included	0	0	0	1	2	3
Week 2	N	3	3	6	2	3	5
	MEAN, GEO MEAN	2210.960, 1988.760	1801.540, 1666.700	2006.250, 1820.620	5.820, 5.817	7.086, 7.018	6.580, 6.511
	SD, SE	1110.8900, 641.3700	893.3000, 515.7470	929.0360, 379.2770	0.2185, 0.1545	1.2076, 0.6972	1.1057, 0.4945
	MEDIAN	2388.510	1485.680	1937.100	5.820	7.004	5.974
	MIN, MAX	1021.988, 3222.372	1109.080, 2809.857	1021.988, 3222.372	5.665, 5.974	5.922, 8.333	5.665, 8.333
	5%, 95%	1021.990, 3222.370	1109.080, 2809.860	1021.990, 3222.370	5.665, 5.974	5.922, 8.333	5.665, 8.333
	BLQ Values Included	0	0	0	2	2	4
Week 3	N	2	3	5	4	3	7
	MEAN, GEO MEAN	1369.010, 1007.190	1623.870, 1555.350	1521.930, 1307.200	4.982, 4.874	4.354, 4.047	4.713, 4.501
	SD, SE	1311.2900, 927.2220	590.2740, 340.7950	789.6630, 353.1480	1.1782, 0.5891	2.0409, 1.1783	1.4816, 0.5600
	MEDIAN	1369.010	1483.110	1483.110	5.113	3.873	4.252
	MIN, MAX	441.785, 2296.228	1116.706, 2271.802	441.785, 2296.228	3.708, 5.994	2.596, 6.592	2.596, 6.592
	5%, 95%	441.785, 2296.230	1116.710, 2271.800	441.785, 2296.230	3.708, 5.994	2.596, 6.592	2.596, 6.592
	BLQ Values Included	0	0	0	4	3	7
Overall*	N	3	3	6	4	3	7
	MEAN, GEO MEAN	2358.570, 1983.780	1608.710, 1519.950	1983.640, 1735.450	4.970, 4.865	5.427, 5.370	5.166, 5.075
	SD, SE	1359.2100, 784.7380	695.7730, 401.7050	1049.4300, 428.4280	1.1646, 0.5823	0.9536, 0.5505	1.0202, 0.3856
	MEDIAN	3075.810	1254.540	1832.430	5.099	5.439	5.439
	MIN, MAX	790.974, 3208.920	1161.270, 2410.310	790.974, 3208.920	3.708, 5.974	4.467, 6.374	3.708, 6.374
	5%, 95%	790.974, 3208.920	1161.270, 2410.310	790.974, 3208.920	3.708, 5.974	4.467, 6.374	3.708, 6.374

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Nicotine (nmol/24hr)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	2	1	3
	MEAN, GEO MEAN	14331.700, 12198.500	4905.960, 4586.580	9618.830, 7479.920	8.568, 8.411	4.080, 4.080	7.072, 6.609
	SD, SE	8085.8500, 4668.3700	2292.4100, 1323.5200	7409.9900, 3025.1100	2.3080, 1.6320	NA, NA	3.0623, 1.7680
	MEDIAN	18042.800	3934.140	6290.340	8.568	4.080	6.936
	MIN, MAX	5056.480, 19895.897	3259.536, 7524.195	3259.536, 19895.897	6.936, 10.200	4.080, 4.080	4.080, 10.200
	5%, 95%	5056.480, 19895.900	3259.540, 7524.200	3259.540, 19895.900	6.936, 10.200	NA, NA	4.080, 10.200
	BLQ Values Included	0	0	0	2	1	3
Week 2	N	3	3	6		2	2
	MEAN, GEO MEAN	9324.810, 8030.610	7091.660, 6235.020	8208.240, 7076.090		7.548, 6.393	7.548, 6.393
	SD, SE	5185.5600, 2993.8900	4448.8200, 2568.5300	4490.9800, 1833.4400		5.6738, 4.0120	5.6738, 4.0120
	MEDIAN	11101.500	5608.210	8354.880		7.548	7.548
	MIN, MAX	3484.431, 13388.466	3574.098, 12092.675	3484.431, 13388.466		3.536, 11.560	3.536, 11.560
	5%, 95%	3484.430, 13388.500	3574.100, 12092.700	3484.430, 13388.500		3.536, 11.560	3.536, 11.560
	BLQ Values Included	0	0	0		2	2
Week 3	N	2	3	5	2	2	4
	MEAN, GEO MEAN	5166.300, 4177.410	6564.500, 6173.720	6005.220, 5280.690	6.569, 6.554	7.582, 6.827	7.076, 6.689
	SD, SE	4298.8100, 3039.7200	2592.1300, 1496.5700	2926.7700, 1308.8900	0.6350, 0.4490	4.6641, 3.2980	2.7799, 1.3899
	MEDIAN	5166.300	7103.310	7103.310	6.569	7.582	6.569
	MIN, MAX	2126.580, 8206.010	3745.315, 8844.885	2126.580, 8844.885	6.120, 7.018	4.284, 10.880	4.284, 10.880
	5%, 95%	2126.580, 8206.010	3745.320, 8844.890	2126.580, 8844.890	6.120, 7.018	4.284, 10.880	4.284, 10.880
	BLQ Values Included	0	0	0	2	2	4
Overall*	N	3	3	6	3	3	6
	MEAN, GEO MEAN	10755.600, 8996.480	6187.370, 5801.020	8471.510, 7224.180	7.915, 7.760	8.802, 7.931	8.359, 7.845
	SD, SE	6339.1500, 3659.9100	2859.8300, 1651.1200	5060.2400, 2065.8400	1.9937, 1.1511	4.2013, 2.4256	2.9810, 1.2170
	MEDIAN	13212.400	4645.650	7066.450	7.018	10.880	8.609
	MIN, MAX	3555.830, 15498.700	4429.220, 9487.250	3555.830, 15498.700	6.528, 10.200	3.967, 11.560	3.967, 11.560
	5%, 95%	3555.830, 15498.700	4429.220, 9487.250	3555.830, 15498.700	6.528, 10.200	3.967, 11.560	3.967, 11.560

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Nicotine (ug/24hr)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	2	1	3
	MEAN, GEO MEAN	2324.600, 1978.590	795.746, 743.943	1560.170, 1213.240	1.390, 1.364	0.662, 0.662	1.147, 1.072
	SD, SE	1311.5200, 757.2090	371.8290, 214.6750	1201.9000, 490.6730	0.3741, 0.2645	NA, NA	0.4964, 0.2866
	MEDIAN	2926.540	638.118	1020.290	1.390	0.662	1.125
	MIN, MAX	820.161, 3227.114	528.697, 1220.424	528.697, 3227.114	1.125, 1.654	0.662, 0.662	0.662, 1.654
	5%, 95%	820.161, 3227.110	528.697, 1220.420	528.697, 3227.110	1.125, 1.654	NA, NA	0.662, 1.654
	BLQ Values Included	0	0	0	2	1	3
Week 2	N	3	3	6		2	2
	MEAN, GEO MEAN	1512.490, 1302.570	1150.270, 1011.320	1331.380, 1147.740		1.225, 1.037	1.225, 1.037
	SD, SE	841.0980, 485.6080	721.5990, 416.6150	728.4370, 297.3830		0.9199, 0.6505	0.9199, 0.6505
	MEDIAN	1800.670	909.652	1355.160		1.225	1.225
	MIN, MAX	565.175, 2171.609	579.719, 1961.432	565.175, 2171.609		0.574, 1.875	0.574, 1.875
	5%, 95%	565.175, 2171.610	579.719, 1961.430	565.175, 2171.610		0.574, 1.875	0.574, 1.875
	BLQ Values Included	0	0	0		2	2
Week 3	N	2	3	5	2	2	4
	MEAN, GEO MEAN	837.973, 677.575	1064.760, 1001.380	974.047, 856.528	1.066, 1.063	1.230, 1.108	1.148, 1.085
	SD, SE	697.2670, 493.0420	420.4430, 242.7430	474.7230, 212.3020	0.1025, 0.0725	0.7566, 0.5350	0.4509, 0.2255
	MEDIAN	837.973	1152.160	1152.160	1.066	1.230	1.066
	MIN, MAX	344.931, 1331.015	607.490, 1434.640	344.931, 1434.640	0.993, 1.138	0.695, 1.765	0.695, 1.765
	5%, 95%	344.931, 1331.020	607.490, 1434.640	344.931, 1434.640	0.993, 1.138	0.695, 1.765	0.695, 1.765
	BLQ Values Included	0	0	0	2	2	4
Overall*	N	3	3	6	3	3	6
	MEAN, GEO MEAN	1744.570, 1459.230	1003.590, 940.926	1374.080, 1171.760	1.284, 1.259	1.428, 1.287	1.356, 1.273
	SD, SE	1028.2100, 593.6370	463.8620, 267.8110	820.7720, 335.0790	0.3231, 0.1866	0.6812, 0.3933	0.4833, 0.1973
	MEDIAN	2143.050	753.524	1146.180	1.138	1.765	1.396
	MIN, MAX	576.756, 2513.890	718.420, 1538.830	576.756, 2513.890	1.059, 1.654	0.644, 1.875	0.644, 1.875
	5%, 95%	576.756, 2513.890	718.420, 1538.830	576.756, 2513.890	1.059, 1.654	0.644, 1.875	0.644, 1.875

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Cotinine (nmol/24hr)

Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	2	6
	MEAN, GEO MEAN	20519.900, 14594.600	22557.700, 21545.600	21538.800, 17732.700	21.588, 20.493	24.244, 21.582	22.473, 20.850
	SD, SE	15520.1000, 8960.5200	8433.2900, 4868.9600	11226.9000, 4583.3600	8.3176, 4.1588	15.6186, 11.0440	9.6010, 3.9196
	MEDIAN	23030.200	20668.900	21849.600	19.360	24.244	19.360
	MIN, MAX	3897.624, 34631.742	15229.032, 31775.275	3897.624, 34631.742	14.630, 33.000	13.200, 35.288	13.200, 35.288
	5%, 95%	3897.620, 34631.700	15229.000, 31775.300	3897.620, 34631.700	14.630, 33.000	13.200, 35.288	13.200, 35.288
Week 2	BLQ Values Included	0	0	0	4	2	6
	N	3	3	6	4	3	7
	MEAN, GEO MEAN	19603.500, 16623.700	24282.000, 23633.000	21942.800, 19820.900	24.778, 23.960	26.822, 23.829	25.654, 23.904
	SD, SE	11343.8000, 6549.3200	6492.9000, 3748.6800	8654.6000, 3533.2300	7.3029, 3.6514	13.6303, 7.8694	9.4756, 3.5815
	MEDIAN	23209.000	26974.000	25091.500	24.365	31.625	30.250
	MIN, MAX	6895.195, 28706.310	16876.134, 28995.975	6895.195, 28995.975	18.480, 31.900	11.440, 37.400	11.440, 37.400
Week 3	5%, 95%	6895.200, 28706.300	16876.100, 28996.000	6895.200, 28996.000	18.480, 31.900	11.440, 37.400	11.440, 37.400
	BLQ Values Included	0	0	0	4	3	7
	N	2	3	5	4	3	7
	MEAN, GEO MEAN	16931.500, 8752.580	19312.100, 18375.600	18359.900, 13658.400	26.604, 26.029	16.903, 16.673	22.446, 21.506
	SD, SE	20497.3000, 14493.8000	6996.5000, 4039.4300	11454.7000, 5122.7000	6.2922, 3.1461	3.4686, 2.0026	7.1197, 2.6910
	MEDIAN	16931.500	20410.500	20410.500	27.302	16.170	20.680
Overall*	MIN, MAX	2437.770, 31425.320	11831.363, 25694.435	2437.770, 31425.320	19.800, 32.010	13.860, 20.680	13.860, 32.010
	5%, 95%	2437.770, 31425.300	11831.400, 25694.400	2437.770, 31425.300	19.800, 32.010	13.860, 20.680	13.860, 32.010
	BLQ Values Included	0	0	0	4	3	7
	N	3	3	6	4	4	8
	MEAN, GEO MEAN	19705.900, 14767.900	22050.600, 21235.000	20878.300, 17708.700	24.323, 23.769	22.875, 21.190	23.599, 22.442
	SD, SE	13906.7000, 8029.0200	7109.4200, 4104.6300	9961.1900, 4066.6400	6.0605, 3.0302	9.9295, 4.9647	7.6547, 2.7064
Overall*	MEDIAN	23119.600	22684.500	22902.100	23.467	22.605	23.467
	MIN, MAX	4410.200, 31587.800	14645.500, 28821.900	4410.200, 31587.800	18.605, 31.753	12.833, 33.457	12.833, 33.457
	5%, 95%	4410.200, 31587.800	14645.500, 28821.900	4410.200, 31587.800	18.605, 31.753	12.833, 33.457	12.833, 33.457

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 44 of 7)

Biomarker: Total Cotinine (ug/24hr)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	2	6
	MEAN, GEO MEAN	3615.600, 2571.560	3974.670, 3796.340	3795.140, 3124.500	3.804, 3.611	4.272, 3.803	3.960, 3.674
	SD, SE	2734.6400, 1578.8400	1485.9500, 857.9110	1978.1800, 807.5880	1.4656, 0.7328	2.7521, 1.9460	1.6917, 0.6906
	MEDIAN	4057.930	3641.860	3849.890	3.412	4.272	3.412
	MIN, MAX	686.761, 6102.113	2683.355, 5598.803	686.761, 6102.113	2.578, 5.815	2.326, 6.218	2.326, 6.218
	5%, 95%	686.761, 6102.110	2683.360, 5598.800	686.761, 6102.110	2.578, 5.815	2.326, 6.218	2.326, 6.218
	BLQ Values Included	0	0	0	4	2	6
Week 2	N	3	3	6	4	3	7
	MEAN, GEO MEAN	3454.140, 2929.090	4278.500, 4164.130	3866.320, 3492.440	4.366, 4.222	4.726, 4.199	4.520, 4.212
	SD, SE	1998.7700, 1153.9900	1144.0500, 660.5170	1524.9400, 622.5540	1.2869, 0.6435	2.4015, 1.3865	1.6696, 0.6310
	MEDIAN	4089.420	4752.820	4421.120	4.293	5.572	5.330
	MIN, MAX	1214.933, 5058.052	2973.575, 5109.091	1214.933, 5109.091	3.256, 5.621	2.016, 6.590	2.016, 6.590
	5%, 95%	1214.930, 5058.050	2973.580, 5109.090	1214.930, 5109.090	3.256, 5.621	2.016, 6.590	2.016, 6.590
	BLQ Values Included	0	0	0	4	3	7
Week 3	N	2	3	5	4	3	7
	MEAN, GEO MEAN	2983.340, 1542.200	3402.790, 3237.790	3235.010, 2406.610	4.688, 4.586	2.978, 2.938	3.955, 3.789
	SD, SE	3611.6200, 2553.8000	1232.7800, 711.7480	2018.3200, 902.6200	1.1087, 0.5544	0.6113, 0.3530	1.2545, 0.4742
	MEDIAN	2983.340	3596.320	3596.320	4.811	2.849	3.644
	MIN, MAX	429.535, 5537.141	2084.686, 4527.359	429.535, 5537.141	3.489, 5.640	2.442, 3.644	2.442, 5.640
	5%, 95%	429.535, 5537.140	2084.690, 4527.360	429.535, 5537.140	3.489, 5.640	2.442, 3.644	2.442, 5.640
	BLQ Values Included	0	0	0	4	3	7
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	3472.180, 2602.110	3885.320, 3741.600	3678.750, 3120.270	4.286, 4.188	4.031, 3.734	4.158, 3.954
	SD, SE	2450.3600, 1414.7100	1252.6800, 723.2350	1755.1600, 716.5410	1.0681, 0.5341	1.7497, 0.8748	1.3489, 0.4769
	MEDIAN	4073.680	3997.000	4035.340	4.135	3.983	4.135
	MIN, MAX	777.076, 5565.770	2580.540, 5078.420	777.076, 5565.770	3.278, 5.595	2.261, 5.895	2.261, 5.895
	5%, 95%	777.076, 5565.770	2580.540, 5078.420	777.076, 5565.770	3.278, 5.595	2.261, 5.895	2.261, 5.895

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Cotinine (nmol/24hr)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	3	7
	MEAN, GEO MEAN	7447.930, 6580.250	8784.550, 8271.040	8116.240, 7377.370	12,002, 9,306	6,909, 6,393	9,819, 7,923
	SD, SE	3854.3400, 2225.3100	3413.1500, 1970.5800	3337.3900, 1362.4800	10,708.1, 5,354.0	3,115.3, 1,798.6	8,244.9, 3,116.3
	MEDIAN	8796.400	9681.650	9239.020	7,812	7,062	7,062
	MIN, MAX	3100.528, 10446.873	5012.448, 11659.550	3100.528, 11659.550	4,588, 27,797	3,720, 9,945	3,720, 27,797
	5%, 95%	3100.530, 10446.900	5012.450, 11659.600	3100.530, 11659.600	4,588, 27,797	3,720, 9,945	3,720, 27,797
	BLQ Values Included	0	0	0	3	3	6
Week 2	N	3	3	6	4	4	8
	MEAN, GEO MEAN	6966.870, 6705.080	10347.600, 9953.410	8657.220, 8169.360	6,983, 6,752	7,374, 6,742	7,179, 6,747
	SD, SE	2243.0800, 1295.0400	3472.8300, 2005.0400	3203.9800, 1308.0200	2,058.1, 1,029.0	3,158.1, 1,579.1	2,476.6, 0,875.6
	MEDIAN	7302.800	10102.000	8162.920	6,867	7,867	7,673
	MIN, MAX	4574.775, 9023.046	7004.052, 13936.670	4574.775, 13936.670	5,208, 8,990	3,224, 10,540	3,224, 10,540
	5%, 95%	4574.780, 9023.050	7004.050, 13936.700	4574.780, 13936.700	5,208, 8,990	3,224, 10,540	3,224, 10,540
	BLQ Values Included	0	0	0	4	4	8
Week 3	N	2	3	5	3	4	7
	MEAN, GEO MEAN	7079.080, 5030.830	7500.510, 7079.280	7331.940, 6175.170	6,989, 6,847	6,053, 5,664	6,454, 6,143
	SD, SE	7043.3200, 4980.3800	2979.9000, 1720.4500	4110.3900, 1838.2200	1,780.2, 1,027.8	2,698.9, 1,349.4	2,224.6, 0,840.8
	MEDIAN	7079.080	7564.870	7564.870	6,398	5,193	5,828
	MIN, MAX	2098.704, 12059.465	4488.944, 10447.710	2098.704, 12059.465	5,580, 8,990	3,906, 9,920	3,906, 9,920
	5%, 95%	2098.700, 12059.500	4488.940, 10447.700	2098.700, 12059.500	5,580, 8,990	3,906, 9,920	3,906, 9,920
	BLQ Values Included	0	0	0	3	4	7
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	7272.470, 6507.890	8877.540, 8499.390	8075.000, 7437.280	8,819, 8,419	6,885, 6,463	7,852, 7,377
	SD, SE	3687.8300, 2129.1700	2928.4600, 1690.7500	3105.3600, 1267.7600	3,162.9, 1,581.4	2,597.9, 1,298.9	2,871.9, 1,015.4
	MEDIAN	8049.600	10394.400	9222.000	8,218	7,165	7,854
	MIN, MAX	3258.000, 10509.800	5501.810, 10736.400	3258.000, 10736.400	5,704, 13,134	3,617, 9,593	3,617, 13,134
	5%, 95%	3258.000, 10509.800	5501.810, 10736.400	3258.000, 10736.400	5,704, 13,134	3,617, 9,593	3,617, 13,134

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Cotinine (ug/24hr)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	3	7
	MEAN, GEO MEAN	1312.330, 1159.440	1547.840, 1457.360	1430.080, 1299.890	2.115, 1.640	1.217, 1.126	1.730, 1.396
	SD, SE	679.1350, 392.0990	601.3970, 347.2170	588.0490, 240.0700	1.8870, 0.9435	0.5490, 0.3170	1.4529, 0.5492
	MEDIAN	1549.930	1705.910	1627.920	1.377	1.244	1.244
	MIN, MAX	546.313, 1840.739	883.193, 2054.413	546.313, 2054.413	0.808, 4.898	0.655, 1.752	0.655, 4.898
	5%, 95%	546.313, 1840.740	883.193, 2054.410	546.313, 2054.410	0.808, 4.898	0.655, 1.752	0.655, 4.898
	BLQ Values Included	0	0	0	3	3	6
Week 2	N	3	3	6	4	4	8
	MEAN, GEO MEAN	1227.560, 1181.440	1823.240, 1753.790	1525.400, 1439.440	1.231, 1.190	1.299, 1.188	1.265, 1.189
	SD, SE	395.2310, 228.1870	611.9120, 353.2880	564.5420, 230.4730	0.3624, 0.1812	0.5563, 0.2782	0.4362, 0.1542
	MEDIAN	1286.750	1779.970	1438.310	1.210	1.386	1.352
	MIN, MAX	806.075, 1589.861	1234.114, 2455.641	806.075, 2455.641	0.918, 1.584	0.568, 1.857	0.568, 1.857
	5%, 95%	806.075, 1589.860	1234.110, 2455.640	806.075, 2455.640	0.918, 1.584	0.568, 1.857	0.568, 1.857
	BLQ Values Included	0	0	0	4	4	8
Week 3	N	2	3	5	3	4	7
	MEAN, GEO MEAN	1247.340, 886.433	1321.590, 1247.370	1291.890, 1088.070	1.231, 1.206	1.067, 0.998	1.137, 1.082
	SD, SE	1241.0300, 877.5430	525.0590, 303.1430	724.2500, 323.8950	0.3138, 0.1812	0.4756, 0.2378	0.3920, 0.1482
	MEDIAN	1247.340	1332.930	1332.930	1.127	0.915	1.027
	MIN, MAX	369.792, 2124.878	790.952, 1840.887	369.792, 2124.878	0.983, 1.584	0.688, 1.748	0.688, 1.748
	5%, 95%	369.792, 2124.880	790.952, 1840.890	369.792, 2124.880	0.983, 1.584	0.688, 1.748	0.688, 1.748
	BLQ Values Included	0	0	0	3	4	7
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	1281.410, 1146.690	1564.220, 1497.590	1422.820, 1310.450	1.554, 1.483	1.213, 1.139	1.383, 1.300
	SD, SE	649.7970, 375.1610	515.9960, 297.9100	547.1660, 223.3790	0.5573, 0.2786	0.4578, 0.2289	0.5060, 0.1789
	MEDIAN	1418.340	1831.490	1624.920	1.448	1.263	1.384
	MIN, MAX	574.060, 1851.830	969.420, 1891.760	574.060, 1891.760	1.005, 2.314	0.637, 1.690	0.637, 2.314
	5%, 95%	574.060, 1851.830	969.420, 1891.760	574.060, 1891.760	1.005, 2.314	0.637, 1.690	0.637, 2.314

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total 3-hydroxycotinine (nmol/24hr)

Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	2	3	5
	MEAN, GEO MEAN	24791.600, 21723.300	41612.400, 39914.900	33202.000, 29446.300	42.241, 38.693	62.528, 42.850	54.413, 41.136
	SD, SE	15099.3000, 8717.5600	15356.3000, 8865.9600	16444.0000, 6713.2200	23.9631, 16.9445	62.2237, 35.9249	46.9354, 20.9901
	MEDIAN	21746.200	34072.600	32778.000	42.241	39.779	39.779
	MIN, MAX	11447.120, 41181.385	31483.480, 59281.220	11447.120, 59281.220	25.296, 59.185	14.880, 132.925	14.880, 132.925
	5%, 95%	11447.100, 41181.400	31483.500, 59281.200	11447.100, 59281.200	25.296, 59.185	14.880, 132.925	14.880, 132.925
Week 2	N	3	3	6	3	2	5
	MEAN, GEO MEAN	24166.900, 21982.600	45347.300, 39977.300	34757.100, 29644.700	42.395, 37.499	24.273, 21.442	35.146, 29.986
	SD, SE	13076.3000, 7549.6200	28769.8000, 16610.2000	23109.7000, 9434.5000	25.3989, 14.6640	16.0895, 11.3770	22.0406, 9.8569
	MEDIAN	19995.700	33423.900	28940.000	35.960	24.273	35.650
	MIN, MAX	13685.048, 38819.979	24456.168, 78161.850	13685.048, 78161.850	20.832, 70.392	12.896, 35.650	12.896, 70.392
	5%, 95%	13685.000, 38820.000	24456.200, 78161.900	13685.000, 78161.900	20.832, 70.392	12.896, 35.650	12.896, 70.392
Week 3	N	2	3	5	3	2	5
	MEAN, GEO MEAN	14960.900, 11909.700	33116.000, 25344.500	25853.900, 18736.600	27.958, 27.387	27.652, 24.899	27.836, 26.364
	SD, SE	12805.2000, 9054.6400	30639.5000, 17689.7000	24683.3000, 11038.7000	7.1207, 4.1111	17.0102, 12.0280	9.8852, 4.4208
	MEDIAN	14960.900	16042.200	16042.200	25.594	27.652	25.594
	MIN, MAX	5906.262, 24015.545	14817.346, 68488.280	5906.262, 68488.280	22.320, 35.960	15.624, 39.680	15.624, 39.680
	5%, 95%	5906.260, 24015.500	14817.300, 68488.300	5906.260, 68488.300	22.320, 35.960	15.624, 39.680	15.624, 39.680
Overall*	N	3	3	6	3	3	6
	MEAN, GEO MEAN	24088.700, 20855.600	40025.200, 35643.800	32057.000, 27264.900	36.833, 34.881	61.921, 41.943	49.377, 38.249
	SD, SE	14945.9000, 8629.0000	24816.8000, 14328.0000	20295.1000, 8285.4600	14.4738, 8.3564	62.6422, 36.1665	42.9212, 17.5225
	MEDIAN	21919.200	26983.200	25716.000	35.960	38.370	37.165
	MIN, MAX	10346.100, 40000.700	24448.700, 68643.800	10346.100, 68643.800	22.816, 51.724	14.467, 132.925	14.467, 132.925
	5%, 95%	10346.100, 40000.700	24448.700, 68643.800	10346.100, 68643.800	22.816, 51.724	14.467, 132.925	14.467, 132.925

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 48 of 7)

Biomarker: Total 3-hydroxycotinine (ug/24hr)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	2	3	5
	MEAN, GEO MEAN	4764.940, 4175.230	7997.910, 7671.640	6381.420, 5659.580	8.119, 7.437	12.018, 8.236	10.458, 7.907
	SD, SE	2902.0800, 1675.5100	2951.4800, 1704.0400	3160.5300, 1290.2800	4.6054, 3.2565	11.9592, 6.9046	9.0208, 4.0342
	MEDIAN	4179.610	6548.750	6299.940	8.119	7.646	7.646
	MIN, MAX	2200.136, 7915.062	6051.125, 11393.850	2200.136, 11393.850	4.862, 11.375	2.860, 25.548	2.860, 25.548
	5%, 95%	2200.140, 7915.060	6051.130, 11393.900	2200.140, 11393.900	4.862, 11.375	2.860, 25.548	2.860, 25.548
	BLQ Values Included	0	0	0	1	2	3
Week 2	N	3	3	6	3	2	5
	MEAN, GEO MEAN	4644.880, 4225.060	8715.750, 7683.640	6680.320, 5697.710	8.148, 7.208	4.666, 4.121	6.755, 5.764
	SD, SE	2513.2700, 1451.0400	5529.5500, 3192.4900	4441.6900, 1813.3100	4.8814, 2.8183	3.0922, 2.1863	4.2360, 1.8944
	MEDIAN	3843.180	6424.070	5562.270	6.912	4.666	6.852
	MIN, MAX	2630.266, 7461.200	4700.475, 15022.708	2630.266, 15022.708	4.004, 13.529	2.479, 6.852	2.479, 13.529
	5%, 95%	2630.270, 7461.200	4700.480, 15022.700	2630.270, 15022.700	4.004, 13.529	2.479, 6.852	2.479, 13.529
	BLQ Values Included	0	0	0	2	2	4
Week 3	N	2	3	5	3	2	5
	MEAN, GEO MEAN	2875.490, 2289.050	6364.890, 4871.210	4969.130, 3601.180	5.374, 5.264	5.315, 4.785	5.350, 5.067
	SD, SE	2461.1600, 1740.3000	5888.9000, 3399.9600	4744.1200, 2121.6400	1.3689, 0.7903	3.2690, 2.3115	1.8999, 0.8496
	MEDIAN	2875.490	3083.320	3083.320	4.919	5.315	4.919
	MIN, MAX	1135.184, 4615.788	2847.894, 13163.447	1135.184, 13163.447	4.290, 6.912	3.003, 7.626	3.003, 7.626
	5%, 95%	1135.180, 4615.790	2847.890, 13163.400	1135.180, 13163.400	4.290, 6.912	3.003, 7.626	3.003, 7.626
	BLQ Values Included	0	0	0	3	2	5
Overall*	N	3	3	6	3	3	6
	MEAN, GEO MEAN	4629.840, 4008.450	7692.840, 6850.720	6161.340, 5240.300	7.079, 6.704	11.901, 8.062	9.490, 7.352
	SD, SE	2872.5900, 1658.4900	4769.7600, 2753.8200	3900.7100, 1592.4600	2.7818, 1.6061	12.0395, 6.9510	8.2493, 3.3678
	MEDIAN	4212.860	5186.170	4942.610	6.912	7.375	7.144
	MIN, MAX	1988.530, 7688.130	4699.040, 13193.300	1988.530, 13193.300	4.385, 9.941	2.781, 25.548	2.781, 25.548
	5%, 95%	1988.530, 7688.130	4699.040, 13193.300	1988.530, 13193.300	4.385, 9.941	2.781, 25.548	2.781, 25.548
	BLQ Values Included	0	0	0	3	2	5

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 49 of 7)

Biomarker: Free 3-hydroxycotinine (nmol/24hr)

Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	4	8
	MEAN, GEO MEAN	21069.900, 18521.300	33503.700, 32205.900	27286.800, 24423.200	23.647, 19.239	31.839, 22.520	27.743, 20.815
	SD, SE	12742.3000, 7356.7600	12057.0000, 6961.1100	13018.2000, 5314.6700	16.1872, 8.0936	24.8055, 12.4027	19.8790, 7.0283
	MEDIAN	18354.800	27146.300	26551.000	21.714	32.462	23.760
	MIN, MAX	9903.928, 34950.846	25955.790, 47408.910	9903.928, 47408.910	8.732, 42.427	5.880, 56.550	5.880, 56.550
	5%, 95%	9903.930, 34950.800	25955.800, 47408.900	9903.930, 47408.900	8.732, 42.427	5.880, 56.550	5.880, 56.550
	BLQ Values Included	0	0	0	0	0	0
Week 2	N	3	3	6	3	4	7
	MEAN, GEO MEAN	18485.500, 16208.500	39076.000, 34277.500	28780.800, 23570.900	35.046, 28.936	20.636, 19.147	26.811, 22.854
	SD, SE	11611.4000, 6703.8700	25209.9000, 14554.9000	20864.7000, 8517.9700	20.9069, 12.0706	8.8182, 4.4091	15.6177, 5.9029
	MEDIAN	14936.900	28809.600	24714.300	46.368	20.185	23.120
	MIN, MAX	9062.489, 31457.230	20619.126, 67799.170	9062.489, 67799.170	10.920, 47.850	10.712, 31.460	10.712, 47.850
	5%, 95%	9062.490, 31457.200	20619.100, 67799.200	9062.490, 67799.200	10.920, 47.850	10.712, 31.460	10.712, 47.850
	BLQ Values Included	0	0	0	0	0	0
Week 3	N	2	3	5	2	3	5
	MEAN, GEO MEAN	12276.900, 10259.200	26289.300, 21251.100	20684.400, 15880.900	25.412, 22.925	19.817, 17.623	22.055, 19.578
	SD, SE	9536.4300, 6743.2700	21906.0000, 12647.4000	17932.5000, 8019.6800	15.5047, 10.9635	11.2455, 6.4926	11.5204, 5.1521
	MEDIAN	12276.900	13910.500	13910.500	25.412	18.228	18.228
	MIN, MAX	5533.662, 19020.205	13375.150, 51582.300	5533.662, 51582.300	14.448, 36.375	9.450, 31.772	9.450, 36.375
	5%, 95%	5533.660, 19020.200	13375.200, 51582.300	5533.660, 51582.300	14.448, 36.375	9.450, 31.772	9.450, 36.375
	BLQ Values Included	0	0	0	0	0	0
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	19602.700, 16784.400	32956.300, 29610.300	26279.500, 22293.300	23.274, 19.026	23.819, 20.460	23.547, 19.730
	SD, SE	12658.3000, 7308.2900	19636.8000, 11337.3000	16487.3000, 6730.9100	15.4570, 7.7285	13.4686, 6.7343	13.4248, 4.7464
	MEDIAN	17437.300	22713.500	21636.100	22.844	24.725	24.725
	MIN, MAX	8166.690, 33204.000	20558.600, 55596.800	8166.690, 55596.800	8.732, 38.675	8.681, 37.147	8.681, 38.675
	5%, 95%	8166.690, 33204.000	20558.600, 55596.800	8166.690, 55596.800	8.732, 38.675	8.681, 37.147	8.681, 38.675
	BLQ Values Included	0	0	0	0	0	0

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., <1.234) will be used as 1.234) for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 50 of 7)

Biomarker: Free 3-hydroxycotinine (ug/24hr)

Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	4	8
	MEAN, GEO MEAN	4049.630, 3559.800	6439.400, 6189.970	5244.520, 4694.150	4.545, 3.697	6.119, 4.328	5.332, 4.000
	SD, SE	2449.0700, 1413.9700	2317.3600, 1337.9300	2502.1100, 1021.4800	3.1111, 1.5555	4.7677, 2.3838	3.8207, 1.3508
	MEDIAN	3527.800	5217.520	5103.110	4.174	6.239	4.567
	MIN, MAX	1903.535, 6717.553	4988.703, 9111.993	1903.535, 9111.993	1.678, 8.154	1.130, 10.869	1.130, 10.869
	5%, 95%	1903.540, 6717.550	4988.700, 9111.990	1903.540, 9111.990	1.678, 8.154	1.130, 10.869	1.130, 10.869
Week 2	BLQ Values Included	0	0	0	0	0	0
	N	3	3	6	3	4	7
	MEAN, GEO MEAN	3552.920, 3115.270	7510.400, 6588.160	5531.660, 4530.330	6.736, 5.562	3.966, 3.680	5.153, 4.393
	SD, SE	2231.7200, 1288.4800	4845.3400, 2797.4600	4010.1900, 1637.1500	4.0183, 2.3200	1.6950, 0.8475	3.0018, 1.1346
	MEDIAN	2870.880	5537.200	4750.100	8.912	3.880	4.444
	MIN, MAX	1741.810, 6046.080	3962.996, 13031.000	1741.810, 13031.000	2.099, 9.197	2.059, 6.047	2.059, 9.197
Week 3	5%, 95%	1741.810, 6046.080	3963.000, 13031.000	1741.810, 13031.000	2.099, 9.197	2.059, 6.047	2.059, 9.197
	BLQ Values Included	0	0	0	0	0	0
	N	2	3	5	2	3	5
	MEAN, GEO MEAN	2359.630, 1971.820	5052.810, 4084.460	3975.540, 3052.300	4.884, 4.406	3.809, 3.387	4.239, 3.763
	SD, SE	1832.9000, 1296.0600	4210.3300, 2430.8400	3446.6400, 1541.3800	2.9797, 2.1070	2.1618, 1.2481	2.2143, 0.9903
	MEDIAN	2359.630	2673.600	2673.600	4.884	3.503	3.503
Overall*	MIN, MAX	1063.570, 3655.683	2570.704, 9914.118	1063.570, 9914.118	2.777, 6.991	1.816, 6.107	1.816, 6.991
	5%, 95%	1063.570, 3655.680	2570.700, 9914.120	1063.570, 9914.120	2.777, 6.991	1.816, 6.107	1.816, 6.991
	BLQ Values Included	0	0	0	0	0	0
	N	3	3	6	4	4	8
	MEAN, GEO MEAN	3767.640, 3225.960	6334.200, 5691.100	5050.920, 4284.770	4.473, 3.657	4.578, 3.932	4.526, 3.792
	SD, SE	2432.9400, 1404.6600	3774.1900, 2179.0300	3168.8600, 1293.6800	2.9707, 1.4853	2.5891, 1.2946	2.5804, 0.9123
Overall*	MEDIAN	3351.450	4365.540	4158.460	4.391	4.752	4.752
	MIN, MAX	1569.640, 6381.820	3951.370, 10685.700	1569.640, 10685.700	1.678, 7.433	1.668, 7.140	1.668, 7.433
	5%, 95%	1569.640, 6381.820	3951.370, 10685.700	1569.640, 10685.700	1.678, 7.433	1.668, 7.140	1.668, 7.433

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., <1.234" will be used as 1.234" for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 51 of 7)

Biomarker: Total Nicotine (nmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	1	2	3
	MEAN, GEO MEAN	11.833, 10.243	6.930, 6.137	9.381, 7.928	0.015, 0.015	0.029, 0.027	0.024, 0.022
	SD, SE	6.6791, 3.8562	3.5278, 2.0368	5.4803, 2.2373	NA, NA	0.0141, 0.0100	0.0129, 0.0074
	MEDIAN	13.088	8.454	8.947	0.015	0.029	0.019
	MIN, MAX	4.615, 17.795	2.896, 9.439	2.896, 17.795	0.015, 0.015	0.019, 0.039	0.015, 0.039
	5%, 95%	4.615, 17.795	2.896, 9.439	2.896, 17.795	NA, NA	0.019, 0.039	0.015, 0.039
	BLQ Values Included	0	0	0	1	2	3
Week 2	N	3	3	6	2	3	5
	MEAN, GEO MEAN	11.371, 10.429	8.138, 7.501	9.755, 8.845	0.021, 0.020	0.038, 0.037	0.031, 0.029
	SD, SE	5.8605, 3.3836	3.5658, 2.0587	4.6862, 1.9131	0.0071, 0.0050	0.0093, 0.0054	0.0118, 0.0053
	MEDIAN	9.627	9.321	9.474	0.021	0.042	0.027
	MIN, MAX	6.581, 17.906	4.131, 10.962	4.131, 17.906	0.016, 0.026	0.027, 0.044	0.016, 0.044
	5%, 95%	6.581, 17.906	4.131, 10.962	4.131, 17.906	0.016, 0.026	0.027, 0.044	0.016, 0.044
	BLQ Values Included	0	0	0	2	2	4
Week 3	N	2	3	5	4	3	7
	MEAN, GEO MEAN	8.146, 7.454	8.716, 8.167	8.488, 7.874	0.021, 0.020	0.022, 0.021	0.021, 0.020
	SD, SE	4.6457, 3.2850	4.0438, 2.3347	3.6972, 1.6534	0.0059, 0.0030	0.0082, 0.0047	0.0064, 0.0024
	MEDIAN	8.146	6.628	6.628	0.020	0.024	0.024
	MIN, MAX	4.861, 11.431	6.143, 13.377	4.861, 13.377	0.015, 0.027	0.013, 0.029	0.013, 0.029
	5%, 95%	4.861, 11.431	6.143, 13.377	4.861, 13.377	0.015, 0.027	0.013, 0.029	0.013, 0.029
	BLQ Values Included	0	0	0	4	3	7
Overall*	N	3	3	6	4	3	7
	MEAN, GEO MEAN	10.807, 9.848	7.928, 7.381	9.367, 8.525	0.021, 0.020	0.030, 0.030	0.025, 0.024
	SD, SE	5.2014, 3.0030	3.4391, 1.9856	4.2474, 1.7340	0.0061, 0.0031	0.0047, 0.0027	0.0072, 0.0027
	MEDIAN	11.358	8.134	9.697	0.021	0.032	0.025
	MIN, MAX	5.352, 15.711	4.390, 11.259	4.390, 15.711	0.015, 0.027	0.025, 0.034	0.015, 0.034
	5%, 95%	5.352, 15.711	4.390, 11.259	4.390, 15.711	0.015, 0.027	0.025, 0.034	0.015, 0.034

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 52 of ?)

Biomarker: Total Nicotine (ug/mg Creatinin)

Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	1	2	3
	MEAN, GEO MEAN	1.919, 1.662	1.124, 0.995	1.522, 1.286	0.002, 0.002	0.005, 0.004	0.004, 0.003
	SD, SE	1.0830, 0.6232	0.5720, 0.3302	0.8887, 0.3628	NA, NA	0.0021, 0.0015	0.0021, 0.0012
	MEDIAN	2.123	1.371	1.451	0.002	0.005	0.003
	MIN, MAX	0.749, 2.886	0.470, 1.531	0.470, 2.886	0.002, 0.002	0.003, 0.006	0.002, 0.006
	5%, 95%	0.749, 2.886	0.470, 1.531	0.470, 2.886	NA, NA	0.003, 0.006	0.002, 0.006
	BLQ Values Included	0	0	0	1	2	3
Week 2	N	3	3	6	2	3	5
	MEAN, GEO MEAN	1.844, 1.691	1.320, 1.217	1.582, 1.434	0.004, 0.003	0.006, 0.006	0.005, 0.005
	SD, SE	0.9506, 0.5489	0.5784, 0.3339	0.7601, 0.3103	0.0007, 0.0005	0.0017, 0.0010	0.0019, 0.0008
	MEDIAN	1.561	1.512	1.537	0.004	0.007	0.004
	MIN, MAX	1.067, 2.904	0.670, 1.778	0.670, 2.904	0.003, 0.004	0.004, 0.007	0.003, 0.007
	5%, 95%	1.067, 2.904	0.670, 1.778	0.670, 2.904	0.003, 0.004	0.004, 0.007	0.003, 0.007
	BLQ Values Included	0	0	0	2	2	4
Week 3	N	2	3	5	4	3	7
	MEAN, GEO MEAN	1.321, 1.209	1.414, 1.324	1.377, 1.277	0.003, 0.003	0.004, 0.003	0.003, 0.003
	SD, SE	0.7538, 0.5330	0.6562, 0.3789	0.5999, 0.2683	0.0010, 0.0005	0.0015, 0.0009	0.0011, 0.0004
	MEDIAN	1.321	1.075	1.075	0.004	0.004	0.004
	MIN, MAX	0.788, 1.854	0.996, 2.170	0.788, 2.170	0.002, 0.004	0.002, 0.005	0.002, 0.005
	5%, 95%	0.788, 1.854	0.996, 2.170	0.788, 2.170	0.002, 0.004	0.002, 0.005	0.002, 0.005
	BLQ Values Included	0	0	0	4	3	7
Overall*	N	3	3	6	4	3	7
	MEAN, GEO MEAN	1.753, 1.597	1.286, 1.197	1.519, 1.383	0.003, 0.003	0.005, 0.005	0.004, 0.004
	SD, SE	0.8436, 0.4870	0.5577, 0.3220	0.6888, 0.2812	0.0010, 0.0005	0.0010, 0.0006	0.0013, 0.0005
	MEDIAN	1.842	1.319	1.573	0.004	0.005	0.004
	MIN, MAX	0.868, 2.548	0.712, 1.826	0.712, 2.548	0.002, 0.004	0.004, 0.006	0.002, 0.006
	5%, 95%	0.868, 2.548	0.712, 1.826	0.712, 2.548	0.002, 0.004	0.004, 0.006	0.002, 0.006

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 53 of 7)

Biomarker: Free Nicotine (nmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	2	1	3
	MEAN, GEO MEAN	9.355, 8.398	3.908, 3.497	6.631, 5.419	0.005, 0.004	0.005, 0.005	0.005, 0.005
	SD, SE	4.5544, 2.6295	1.9305, 1.1146	4.3231, 1.7649	0.0007, 0.0005	NA, NA	0.0006, 0.0003
	MEDIAN	11.224	4.646	5.003	0.005	0.005	0.005
	MIN, MAX	4.163, 12.677	1.717, 5.360	1.717, 12.677	0.004, 0.005	0.005, 0.005	0.004, 0.005
	5%, 95%	4.163, 12.677	1.717, 5.360	1.717, 12.677	0.004, 0.005	NA, NA	0.004, 0.005
	BLQ Values Included	0	0	0	2	1	3
Week 2	N	3	3	6		2	2
	MEAN, GEO MEAN	7.655, 6.831	5.173, 4.551	6.414, 5.576		0.008, 0.006	0.008, 0.006
	SD, SE	4.2280, 2.4410	2.7852, 1.6080	3.4787, 1.4202		0.0064, 0.0045	0.0064, 0.0045
	MEDIAN	7.258	5.707	6.483		0.008	0.008
	MIN, MAX	3.639, 12.067	2.159, 7.652	2.159, 12.067		0.003, 0.012	0.003, 0.012
	5%, 95%	3.639, 12.067	2.159, 7.652	2.159, 12.067		0.003, 0.012	0.003, 0.012
	BLQ Values Included	0	0	0		2	2
Week 3	N	2	3	5	2	2	4
	MEAN, GEO MEAN	5.211, 5.015	5.608, 5.258	5.449, 5.159	0.006, 0.005	0.006, 0.005	0.006, 0.005
	SD, SE	2.0011, 1.4150	2.5268, 1.4588	2.0593, 0.9210	0.0021, 0.0015	0.0035, 0.0025	0.0024, 0.0012
	MEDIAN	5.211	4.773	4.773	0.006	0.006	0.006
	MIN, MAX	3.796, 6.626	3.605, 8.447	3.605, 8.447	0.004, 0.007	0.003, 0.008	0.003, 0.008
	5%, 95%	3.796, 6.626	3.605, 8.447	3.605, 8.447	0.004, 0.007	0.003, 0.008	0.003, 0.008
	BLQ Values Included	0	0	0	2	2	4
Overall*	N	3	3	6	3	3	6
	MEAN, GEO MEAN	7.855, 7.202	4.896, 4.578	6.376, 5.742	0.005, 0.005	0.008, 0.007	0.006, 0.006
	SD, SE	3.5074, 2.0250	2.1454, 1.2386	3.0639, 1.2508	0.0012, 0.0007	0.0040, 0.0023	0.0032, 0.0013
	MEDIAN	9.241	4.653	5.903	0.004	0.008	0.005
	MIN, MAX	3.866, 10.457	2.883, 7.153	2.883, 10.457	0.004, 0.006	0.004, 0.012	0.004, 0.012
	5%, 95%	3.866, 10.457	2.883, 7.153	2.883, 10.457	0.004, 0.006	0.004, 0.012	0.004, 0.012

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 54 of 7)

Biomarker: Free Nicotine (ug/mg Creatinin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	2	1	3
	MEAN, GEO MEAN	1.517, 1.362	0.634, 0.567	1.076, 0.879	0.001, 0.001	0.001, 0.001	0.001, 0.001
	SD, SE	0.7389, 0.4266	0.3133, 0.1809	0.7014, 0.2863	0.0000, 0.0000	NA, NA	0.0000, 0.0000
	MEDIAN	1.821	0.754	0.812	0.001	0.001	0.001
	MIN, MAX	0.675, 2.056	0.278, 0.869	0.278, 2.056	0.001, 0.001	0.001, 0.001	0.001, 0.001
	5%, 95%	0.675, 2.056	0.278, 0.869	0.278, 2.056	0.001, 0.001	NA, NA	0.001, 0.001
	BLQ Values Included	0	0	0	2	1	3
Week 2	N	3	3	6		2	2
	MEAN, GEO MEAN	1.241, 1.108	0.839, 0.738	1.040, 0.904		0.001, NA	0.001, NA
	SD, SE	0.6858, 0.3959	0.4518, 0.2609	0.5642, 0.2303		0.0014, 0.0010	0.0014, 0.0010
	MEDIAN	1.177	0.926	1.052		0.001	0.001
	MIN, MAX	0.590, 1.957	0.350, 1.241	0.350, 1.957		0.000, 0.002	0.000, 0.002
	5%, 95%	0.590, 1.957	0.350, 1.241	0.350, 1.957		0.000, 0.002	0.000, 0.002
	BLQ Values Included	0	0	0		2	2
Week 3	N	2	3	5	2	2	4
	MEAN, GEO MEAN	0.846, 0.814	0.910, 0.853	0.884, 0.837	0.001, 0.001	0.001, NA	0.001, NA
	SD, SE	0.3246, 0.2295	0.4097, 0.2365	0.3339, 0.1493	0.0000, 0.0000	0.0007, 0.0005	0.0005, 0.0003
	MEDIAN	0.846	0.774	0.774	0.001	0.001	0.001
	MIN, MAX	0.616, 1.075	0.585, 1.370	0.585, 1.370	0.001, 0.001	0.000, 0.001	0.000, 0.001
	5%, 95%	0.616, 1.075	0.585, 1.370	0.585, 1.370	0.001, 0.001	0.000, 0.001	0.000, 0.001
	BLQ Values Included	0	0	0	2	2	4
Overall*	N	3	3	6	3	3	6
	MEAN, GEO MEAN	1.274, 1.168	0.794, 0.742	1.034, 0.931	0.001, 0.001	0.001, NA	0.001, NA
	SD, SE	0.5689, 0.3285	0.3481, 0.2010	0.4971, 0.2029	0.0000, 0.0000	0.0010, 0.0006	0.0006, 0.0003
	MEDIAN	1.499	0.755	0.958	0.001	0.001	0.001
	MIN, MAX	0.627, 1.696	0.467, 1.160	0.467, 1.696	0.001, 0.001	0.000, 0.002	0.000, 0.002
	5%, 95%	0.627, 1.696	0.467, 1.160	0.467, 1.696	0.001, 0.001	0.000, 0.002	0.000, 0.002

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Cotinine (nmol/mg Creatin)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	2	6
	MEAN, GEO MEAN	13.511, 10.048	18.355, 16.426	15.933, 12.847	0.011, 0.010	0.026, 0.024	0.016, 0.014
	SD, SE	10.5711, 6.1032	8.9922, 5.1917	9.1696, 3.7435	0.0048, 0.0024	0.0120, 0.0085	0.0098, 0.0040
	MEDIAN	12.992	22.634	17.813	0.011	0.026	0.015
	MIN, MAX	3.209, 24.332	8.022, 24.408	3.209, 24.408	0.006, 0.017	0.017, 0.034	0.006, 0.034
	5%, 95%	3.209, 24.332	8.022, 24.408	3.209, 24.408	0.006, 0.017	0.017, 0.034	0.006, 0.034
	BLQ Values Included	0	0	0	4	2	6
Week 2	N	3	3	6	4	3	7
	MEAN, GEO MEAN	16.083, 14.140	18.664, 17.252	17.374, 15.619	0.014, 0.013	0.023, 0.020	0.018, 0.016
	SD, SE	9.3691, 5.4093	8.6313, 4.9833	8.1799, 3.3394	0.0066, 0.0033	0.0145, 0.0084	0.0107, 0.0041
	MEDIAN	15.174	18.349	16.762	0.014	0.023	0.014
	MIN, MAX	7.201, 25.873	10.195, 27.449	7.201, 27.449	0.007, 0.023	0.009, 0.038	0.007, 0.038
	5%, 95%	7.201, 25.873	10.195, 27.449	7.201, 27.449	0.007, 0.023	0.009, 0.038	0.007, 0.038
	BLQ Values Included	0	0	0	4	3	7
Week 3	N	2	3	5	4	3	7
	MEAN, GEO MEAN	14.863, 10.507	17.379, 15.650	16.373, 13.344	0.018, 0.017	0.018, 0.017	0.018, 0.017
	SD, SE	14.8662, 10.5120	8.5251, 4.9219	9.6689, 4.3241	0.0050, 0.0025	0.0064, 0.0037	0.0051, 0.0019
	MEDIAN	14.863	19.648	19.648	0.018	0.021	0.021
	MIN, MAX	4.351, 25.375	7.949, 24.540	4.351, 25.375	0.013, 0.023	0.011, 0.023	0.011, 0.023
	5%, 95%	4.351, 25.375	7.949, 24.540	4.351, 25.375	0.013, 0.023	0.011, 0.023	0.011, 0.023
	BLQ Values Included	0	0	0	4	3	7
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	14.732, 12.041	18.133, 16.559	16.432, 14.120	0.015, 0.014	0.024, 0.022	0.019, 0.018
	SD, SE	10.1521, 5.8613	8.2106, 4.7404	8.4653, 3.4559	0.0043, 0.0021	0.0083, 0.0041	0.0077, 0.0027
	MEDIAN	14.083	21.841	17.962	0.016	0.026	0.018
	MIN, MAX	4.920, 25.193	8.722, 23.835	4.920, 25.193	0.009, 0.018	0.012, 0.030	0.009, 0.030
	5%, 95%	4.920, 25.193	8.722, 23.835	4.920, 25.193	0.009, 0.018	0.012, 0.030	0.009, 0.030

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Cotinine (ug/mg Creatinine)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	2	6
	MEAN, GEO MEAN	2.380, 1.770	3.234, 2.894	2.807, 2.263	0.002, 0.002	0.005, 0.004	0.003, 0.002
	SD, SE	1.8627, 1.0754	1.5848, 0.9150	1.6159, 0.6597	0.0008, 0.0004	0.0021, 0.0015	0.0017, 0.0007
	MEDIAN	2.289	3.988	3.139	0.002	0.005	0.003
	MIN, MAX	0.565, 4.287	1.413, 4.301	0.565, 4.301	0.001, 0.003	0.003, 0.006	0.001, 0.006
	5%, 95%	0.565, 4.287	1.413, 4.301	0.565, 4.301	0.001, 0.003	0.003, 0.006	0.001, 0.006
Week 2	BLQ Values Included	0	0	0	4	2	6
	N	3	3	6	4	3	7
	MEAN, GEO MEAN	2.834, 2.492	3.289, 3.040	3.061, 2.752	0.002, 0.002	0.004, 0.004	0.003, 0.003
	SD, SE	1.6508, 0.9531	1.5213, 0.8783	1.4415, 0.5885	0.0013, 0.0006	0.0025, 0.0015	0.0020, 0.0008
	MEDIAN	2.674	3.233	2.954	0.002	0.004	0.002
	MIN, MAX	1.269, 4.559	1.796, 4.837	1.269, 4.837	0.001, 0.004	0.002, 0.007	0.001, 0.007
Week 3	5%, 95%	1.269, 4.559	1.796, 4.837	1.269, 4.837	0.001, 0.004	0.002, 0.007	0.001, 0.007
	BLQ Values Included	0	0	0	4	3	7
	N	2	3	5	4	3	7
	MEAN, GEO MEAN	2.619, 1.852	3.062, 2.758	2.885, 2.352	0.003, 0.003	0.003, 0.003	0.003, 0.003
	SD, SE	2.6191, 1.8520	1.5019, 0.8671	1.7035, 0.7618	0.0012, 0.0006	0.0012, 0.0007	0.0011, 0.0004
	MEDIAN	2.619	3.462	3.462	0.003	0.004	0.004
Overall*	MIN, MAX	0.767, 4.471	1.401, 4.324	0.767, 4.471	0.002, 0.004	0.002, 0.004	0.002, 0.004
	5%, 95%	0.767, 4.471	1.401, 4.324	0.767, 4.471	0.002, 0.004	0.002, 0.004	0.002, 0.004
	BLQ Values Included	0	0	0	4	3	7
	N	3	3	6	4	4	8
	MEAN, GEO MEAN	2.596, 2.122	3.195, 2.918	2.896, 2.488	0.002, 0.002	0.004, 0.004	0.003, 0.003
	SD, SE	1.7887, 1.0327	1.4466, 0.8352	1.4915, 0.6089	0.0010, 0.0005	0.0017, 0.0009	0.0017, 0.0006
Overall*	MEDIAN	2.482	3.848	3.165	0.003	0.005	0.003
	MIN, MAX	0.867, 4.439	1.537, 4.200	0.867, 4.439	0.001, 0.003	0.002, 0.006	0.001, 0.006
	5%, 95%	0.867, 4.439	1.537, 4.200	0.867, 4.439	0.001, 0.003	0.002, 0.006	0.001, 0.006
	BLQ Values Included	0	0	0	4	3	7

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Cotinine (nmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	3	7
	MEAN, GEO MEAN	4.952, 4.530	7.459, 6.305	6.206, 5.345	0.006, 0.005	0.007, 0.006	0.006, 0.006
	SD, SE	2.3935, 1.3819	4.4571, 2.5733	3.4820, 1.4215	0.0041, 0.0020	0.0029, 0.0017	0.0034, 0.0013
	MEDIAN	4.962	8.305	6.151	0.005	0.005	0.005
	MIN, MAX	2.553, 7.340	2.640, 11.433	2.553, 11.433	0.003, 0.012	0.005, 0.010	0.003, 0.012
	5%, 95%	2.553, 7.340	2.640, 11.433	2.553, 11.433	0.003, 0.012	0.005, 0.010	0.003, 0.012
	BLQ Values Included	0	0	0	3	3	6
Week 2	N	3	3	6	4	4	8
	MEAN, GEO MEAN	5.895, 5.703	8.269, 7.266	7.082, 6.437	0.004, 0.004	0.007, 0.006	0.005, 0.005
	SD, SE	1.9382, 1.1190	5.2339, 3.0218	3.7617, 1.5357	0.0016, 0.0008	0.0034, 0.0017	0.0028, 0.0010
	MEDIAN	4.778	6.393	5.586	0.004	0.006	0.005
	MIN, MAX	4.774, 8.133	4.231, 14.182	4.231, 14.182	0.002, 0.006	0.003, 0.011	0.002, 0.011
	5%, 95%	4.774, 8.133	4.231, 14.182	4.231, 14.182	0.002, 0.006	0.003, 0.011	0.002, 0.011
	BLQ Values Included	0	0	0	4	4	8
Week 3	N	2	3	5	3	4	7
	MEAN, GEO MEAN	6.742, 6.040	6.759, 6.029	6.752, 6.033	0.005, 0.005	0.006, 0.005	0.005, 0.005
	SD, SE	4.2370, 2.9960	3.5104, 2.0267	3.2634, 1.4594	0.0012, 0.0007	0.0017, 0.0009	0.0014, 0.0005
	MEDIAN	6.742	7.282	7.282	0.006	0.006	0.006
	MIN, MAX	3.746, 9.738	3.016, 9.978	3.016, 9.978	0.004, 0.006	0.003, 0.007	0.003, 0.007
	5%, 95%	3.746, 9.738	3.016, 9.978	3.016, 9.978	0.004, 0.006	0.003, 0.007	0.003, 0.007
	BLQ Values Included	0	0	0	3	4	7
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	5.655, 5.326	7.496, 6.674	6.575, 5.962	0.005, 0.005	0.007, 0.006	0.006, 0.006
	SD, SE	2.4525, 1.4160	3.8867, 2.2440	3.0766, 1.2560	0.0008, 0.0004	0.0024, 0.0012	0.0018, 0.0006
	MEDIAN	4.868	8.225	6.547	0.005	0.007	0.005
	MIN, MAX	3.692, 8.404	3.296, 10.966	3.296, 10.966	0.004, 0.006	0.004, 0.009	0.004, 0.009
	5%, 95%	3.692, 8.404	3.296, 10.966	3.296, 10.966	0.004, 0.006	0.004, 0.009	0.004, 0.009

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Timepoint	Statistic	Smokers		Non-Smokers		Overall
		Male	Female	Male	Female	
Week 1	N	3	3	4	3	7
	MEAN, GEO MEAN	0.872, 0.798	1.314, 1.111	0.001, 0.001	0.001, 0.001	0.001, 0.001
	SD, SE	0.4215, 0.2434	0.7852, 0.4533	0.0005, 0.0003	0.0006, 0.0003	0.0005, 0.0002
	MEDIAN	0.874	1.463	0.001	0.001	0.001
	MIN, MAX	0.450, 1.293	0.465, 2.014	0.001, 0.002	0.001, 0.002	0.001, 0.002
Week 2	5%, 95%	0.450, 1.293	0.465, 2.014	0.001, 0.002	0.001, 0.002	0.001, 0.002
	BLQ Values Included	0	0	3	3	6
Week 3	N	3	3	4	4	8
	MEAN, GEO MEAN	1.039, 1.005	1.457, 1.280	0.001, NA	0.001, 0.001	0.001, NA
	SD, SE	0.3415, 0.1972	0.9222, 0.5324	0.0005, 0.0003	0.0005, 0.0003	0.0005, 0.0002
	MEDIAN	0.842	1.126	0.001	0.001	0.001
	MIN, MAX	0.841, 1.433	0.746, 2.499	0.000, 0.001	0.001, 0.002	0.000, 0.002
Overall*	5%, 95%	0.841, 1.433	0.746, 2.499	0.000, 0.001	0.001, 0.002	0.000, 0.002
	BLQ Values Included	0	0	4	4	8
Week 1	N	2	3	3	4	7
	MEAN, GEO MEAN	1.188, 1.064	1.191, 1.062	0.001, 0.001	0.001, 0.001	0.001, 0.001
	SD, SE	0.7467, 0.5280	0.6187, 0.3572	0.0000, 0.0000	0.0000, 0.0000	0.0000, 0.0000
	MEDIAN	1.188	1.283	0.001	0.001	0.001
	MIN, MAX	0.660, 1.716	0.531, 1.758	0.001, 0.001	0.001, 0.001	0.001, 0.001
Overall*	5%, 95%	0.660, 1.716	0.531, 1.758	0.001, 0.001	0.001, 0.001	0.001, 0.001
	BLQ Values Included	0	0	3	4	7
Week 2	N	3	3	4	4	8
	MEAN, GEO MEAN	0.997, 0.939	1.321, 1.176	0.001, 0.001	0.001, 0.001	0.001, 0.001
	SD, SE	0.4320, 0.2494	0.6846, 0.3952	0.0000, 0.0000	0.0005, 0.0003	0.0004, 0.0001
	MEDIAN	0.858	1.449	0.001	0.001	0.001
	MIN, MAX	0.651, 1.481	0.581, 1.932	0.001, 0.001	0.001, 0.002	0.001, 0.002
Overall*	5%, 95%	0.651, 1.481	0.581, 1.932	0.001, 0.001	0.001, 0.002	0.001, 0.002

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., <1.234) will be used as '1.234' for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total 3-hydroxycotinine (nmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	2	3	5
	MEAN, GEO MEAN	15.979, 14.956	36.794, 30.430	26.386, 21.334	0.022, 0.022	0.051, 0.041	0.040, 0.032
	SD, SE	6.9296, 4.0008	28.8498, 16.6564	21.9570, 8.9639	0.0042, 0.0030	0.0400, 0.0231	0.0326, 0.0146
	MEDIAN	15.278	22.427	20.188	0.022	0.039	0.025
	MIN, MAX	9.426, 23.232	17.948, 70.006	9.426, 70.006	0.019, 0.025	0.019, 0.096	0.019, 0.096
	5%, 95%	9.426, 23.232	17.948, 70.006	9.426, 70.006	0.019, 0.025	0.019, 0.096	0.019, 0.096
	BLQ Values Included	0	0	0	1	2	3
Week 2	N	3	3	6	3	2	5
	MEAN, GEO MEAN	19.232, 18.698	38.488, 29.184	28.860, 23.360	0.022, 0.022	0.019, 0.017	0.021, 0.020
	SD, SE	5.6416, 3.2572	35.6930, 20.6074	25.1708, 10.2759	0.0064, 0.0037	0.0106, 0.0075	0.0073, 0.0032
	MEDIAN	18.022	21.151	19.587	0.026	0.019	0.026
	MIN, MAX	14.293, 25.380	14.775, 79.538	14.293, 79.538	0.015, 0.026	0.011, 0.026	0.011, 0.026
	5%, 95%	14.293, 25.380	14.775, 79.538	14.293, 79.538	0.015, 0.026	0.011, 0.026	0.011, 0.026
	BLQ Values Included	0	0	0	2	2	4
Week 3	N	2	3	5	3	2	5
	MEAN, GEO MEAN	14.967, 14.298	30.402, 21.584	24.228, 18.306	0.021, 0.021	0.020, 0.018	0.021, 0.020
	SD, SE	6.2579, 4.4250	30.8849, 17.8314	23.6263, 10.5660	0.0057, 0.0033	0.0113, 0.0080	0.0070, 0.0031
	MEDIAN	14.967	15.321	15.321	0.023	0.020	0.023
	MIN, MAX	10.542, 19.392	9.955, 65.930	9.955, 65.930	0.015, 0.026	0.012, 0.028	0.012, 0.028
	5%, 95%	10.542, 19.392	9.955, 65.930	9.955, 65.930	0.015, 0.026	0.012, 0.028	0.012, 0.028
	BLQ Values Included	0	0	0	3	2	5
Overall*	N	3	3	6	3	3	6
	MEAN, GEO MEAN	17.763, 16.956	35.228, 27.172	26.496, 21.465	0.022, 0.022	0.047, 0.035	0.035, 0.028
	SD, SE	6.4453, 3.7212	31.8090, 18.3650	22.6461, 9.2452	0.0025, 0.0015	0.0433, 0.0250	0.0306, 0.0125
	MEDIAN	17.564	19.633	18.599	0.022	0.031	0.024
	MIN, MAX	11.420, 24.306	14.226, 71.825	11.420, 71.825	0.020, 0.025	0.014, 0.096	0.014, 0.096
	5%, 95%	11.420, 24.306	14.226, 71.825	11.420, 71.825	0.020, 0.025	0.014, 0.096	0.014, 0.096

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 60 of 7)

Biomarker: Total 3-hydroxycotinine (ug/mg Creatinine)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	2	3	5
	MEAN, GEO MEAN	3.071, 2.875	7.072, 5.849	5.071, 4.100	0.005, 0.004	0.010, 0.008	0.008, 0.006
	SD, SE	1.3316, 0.7688	5.5448, 3.2013	4.2201, 1.7228	0.0007, 0.0005	0.0074, 0.0043	0.0059, 0.0027
	MEDIAN	2.936	4.310	3.880	0.005	0.007	0.005
	MIN, MAX	1.812, 4.465	3.450, 13.455	1.812, 13.455	0.004, 0.005	0.004, 0.018	0.004, 0.018
	5%, 95%	1.812, 4.465	3.450, 13.455	1.812, 13.455	0.004, 0.005	0.004, 0.018	0.004, 0.018
Week 2	BLQ Values Included	0	0	0	1	2	3
	N	3	3	6	3	2	5
	MEAN, GEO MEAN	3.696, 3.594	7.397, 5.609	5.547, 4.490	0.004, 0.004	0.004, 0.003	0.004, 0.004
	SD, SE	1.0843, 0.6260	6.8601, 3.9607	4.8377, 1.9750	0.0012, 0.0007	0.0021, 0.0015	0.0014, 0.0006
	MEDIAN	3.464	4.065	3.765	0.005	0.004	0.005
	MIN, MAX	2.747, 4.878	2.840, 15.287	2.747, 15.287	0.003, 0.005	0.002, 0.005	0.002, 0.005
Week 3	5%, 95%	2.747, 4.878	2.840, 15.287	2.747, 15.287	0.003, 0.005	0.002, 0.005	0.002, 0.005
	BLQ Values Included	0	0	0	2	2	4
	N	2	3	5	3	2	5
	MEAN, GEO MEAN	2.877, 2.748	5.843, 4.148	4.657, 3.518	0.004, 0.004	0.004, 0.003	0.004, 0.004
	SD, SE	1.2028, 0.8505	5.9363, 3.4273	4.5411, 2.0309	0.0010, 0.0006	0.0021, 0.0015	0.0013, 0.0006
	MEDIAN	2.877	2.945	2.945	0.004	0.004	0.004
Overall*	MIN, MAX	2.026, 3.727	1.913, 12.672	1.913, 12.672	0.003, 0.005	0.002, 0.005	0.002, 0.005
	5%, 95%	2.026, 3.727	1.913, 12.672	1.913, 12.672	0.003, 0.005	0.002, 0.005	0.002, 0.005
	BLQ Values Included	0	0	0	3	2	5
	N	3	3	6	3	3	6
	MEAN, GEO MEAN	3.414, 3.259	6.771, 5.222	5.093, 4.126	0.004, 0.004	0.009, 0.007	0.007, 0.005
	SD, SE	1.2389, 0.7153	6.1140, 3.5299	4.3527, 1.7770	0.0006, 0.0003	0.0079, 0.0046	0.0056, 0.0023
Overall*	MEDIAN	3.376	3.773	3.575	0.004	0.006	0.005
	MIN, MAX	2.195, 4.672	2.734, 13.805	2.195, 13.805	0.004, 0.005	0.003, 0.018	0.003, 0.018
	5%, 95%	2.195, 4.672	2.734, 13.805	2.195, 13.805	0.004, 0.005	0.003, 0.018	0.003, 0.018
	BLQ Values Included	0	0	0	3	2	5

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free 3-hydroxycotinine (nmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	4	8
	MEAN, GEO MEAN	13.589, 12.752	29.592, 24.553	21.591, 17.695	0.011, 0.010	0.024, 0.019	0.018, 0.014
	SD, SE	5.8121, 3.3556	22.9539, 13.2525	17.3519, 7.0839	0.0055, 0.0027	0.0157, 0.0079	0.0129, 0.0046
	MEDIAN	12.896	18.489	16.395	0.011	0.024	0.014
	MIN, MAX	8.155, 19.717	14.300, 55.986	8.155, 55.986	0.005, 0.018	0.007, 0.041	0.005, 0.041
	5%, 95%	8.155, 19.717	14.300, 55.986	8.155, 55.986	0.005, 0.018	0.007, 0.041	0.005, 0.041
	BLQ Values Included	0	0	0	0	0	0
Week 2	N	3	3	6	3	4	7
	MEAN, GEO MEAN	14.498, 13.787	33.227, 25.023	23.863, 18.574	0.015, 0.014	0.017, 0.016	0.016, 0.015
	SD, SE	5.6224, 3.2461	31.1085, 17.9605	22.4716, 9.1740	0.0057, 0.0038	0.0074, 0.0037	0.0066, 0.0025
	MEDIAN	13.463	18.231	15.847	0.017	0.018	0.017
	MIN, MAX	9.465, 20.566	12.457, 68.993	9.465, 68.993	0.008, 0.021	0.009, 0.024	0.008, 0.024
	5%, 95%	9.465, 20.566	12.457, 68.993	9.465, 68.993	0.008, 0.021	0.009, 0.024	0.008, 0.024
	BLQ Values Included	0	0	0	0	0	0
Week 3	N	2	3	5	2	3	5
	MEAN, GEO MEAN	12.618, 12.316	23.925, 18.098	19.402, 15.516	0.012, 0.011	0.022, 0.019	0.018, 0.015
	SD, SE	3.8757, 2.7405	22.3492, 12.9033	17.0839, 7.6401	0.0057, 0.0040	0.0125, 0.0072	0.0108, 0.0048
	MEDIAN	12.618	12.774	12.774	0.012	0.026	0.016
	MIN, MAX	9.877, 15.358	9.346, 49.656	9.346, 49.656	0.008, 0.016	0.008, 0.032	0.008, 0.032
	5%, 95%	9.877, 15.358	9.346, 49.656	9.346, 49.656	0.008, 0.016	0.008, 0.032	0.008, 0.032
	BLQ Values Included	0	0	0	0	0	0
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	14.405, 13.693	28.915, 22.609	21.660, 17.595	0.011, 0.010	0.020, 0.018	0.016, 0.013
	SD, SE	5.5050, 3.1783	25.4702, 14.7052	18.2969, 7.4697	0.0050, 0.0025	0.0111, 0.0056	0.0094, 0.0033
	MEDIAN	13.906	16.498	15.202	0.012	0.021	0.014
	MIN, MAX	9.166, 20.142	12.034, 58.212	9.166, 58.212	0.005, 0.016	0.008, 0.032	0.005, 0.032
	5%, 95%	9.166, 20.142	12.034, 58.212	9.166, 58.212	0.005, 0.016	0.008, 0.032	0.005, 0.032
	BLQ Values Included	0	0	0	0	0	0

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., <1.234) will be used as '1.234' for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free 3-hydroxycotinine (ug/mg Creatinin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	4	8
	MEAN, GEO MEAN	2.612, 2.451	5.688, 4.719	4.150, 3.401	0.002, 0.002	0.005, 0.003	0.003, 0.003
	SD, SE	1.1175, 0.6452	4.4121, 2.5473	3.3353, 1.3616	0.0008, 0.0004	0.0031, 0.0016	0.0025, 0.0009
	MEDIAN	2.479	3.554	3.151	0.002	0.005	0.003
	MIN, MAX	1.567, 3.790	2.748, 10.761	1.567, 10.761	0.001, 0.003	0.001, 0.008	0.001, 0.008
	5%, 95%	1.567, 3.790	2.748, 10.761	1.567, 10.761	0.001, 0.003	0.001, 0.008	0.001, 0.008
	BLQ Values Included	0	0	0	0	0	0
Week 2	N	3	3	6	3	4	7
	MEAN, GEO MEAN	2.787, 2.650	6.386, 4.809	4.586, 3.570	0.003, 0.003	0.003, 0.003	0.003, 0.003
	SD, SE	1.0808, 0.6240	5.9789, 3.4519	4.3189, 1.7632	0.0010, 0.0006	0.0015, 0.0008	0.0012, 0.0005
	MEDIAN	2.588	3.504	3.046	0.003	0.003	0.003
	MIN, MAX	1.819, 3.953	2.394, 13.260	1.819, 13.260	0.002, 0.004	0.002, 0.005	0.002, 0.005
	5%, 95%	1.819, 3.953	2.394, 13.260	1.819, 13.260	0.002, 0.004	0.002, 0.005	0.002, 0.005
	BLQ Values Included	0	0	0	0	0	0
Week 3	N	2	3	5	2	3	5
	MEAN, GEO MEAN	2.425, 2.367	4.598, 3.478	3.729, 2.982	0.003, 0.002	0.004, 0.004	0.004, 0.003
	SD, SE	0.7453, 0.5270	4.2957, 2.4801	3.2837, 1.4685	0.0007, 0.0005	0.0021, 0.0012	0.0018, 0.0008
	MEDIAN	2.425	2.455	2.455	0.003	0.005	0.003
	MIN, MAX	1.898, 2.952	1.796, 9.544	1.796, 9.544	0.002, 0.003	0.002, 0.006	0.002, 0.006
	5%, 95%	1.898, 2.952	1.796, 9.544	1.796, 9.544	0.002, 0.003	0.002, 0.006	0.002, 0.006
	BLQ Values Included	0	0	0	0	0	0
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	2.769, 2.632	5.557, 4.346	4.163, 3.382	0.002, 0.002	0.004, 0.004	0.003, 0.003
	SD, SE	1.0587, 0.6113	4.8951, 2.8262	3.5166, 1.4356	0.0010, 0.0005	0.0018, 0.0009	0.0016, 0.0006
	MEDIAN	2.673	3.171	2.922	0.003	0.004	0.003
	MIN, MAX	1.761, 3.872	2.313, 11.188	1.761, 11.188	0.001, 0.003	0.002, 0.006	0.001, 0.006
	5%, 95%	1.761, 3.872	2.313, 11.188	1.761, 11.188	0.001, 0.003	0.002, 0.006	0.001, 0.006
	BLQ Values Included	0	0	0	0	0	0

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Nicotine Gluturonide (nmol/L)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	1	1	2
	MEAN, GEO MEAN	3609.8, 1906.8	1593.8, 1512.8	2601.8, 1698.4	9.3, 9.3	9.3, 9.3	9.3, 9.3
	SD, SE	4207.14, 2428.99	653.29, 377.18	2910.33, 1188.14	NA, NA	NA, NA	0.00, 0.00
	MEDIAN	2052.5	1331.9	1692.2	9.3	9.3	9.3
	MIN, MAX	403.4, 8373.6	1112.1, 2337.4	403.4, 8373.6	9.3, 9.3	9.3, 9.3	9.3, 9.3
	5%, 95%	403.4, 8373.6	1112.1, 2337.4	403.4, 8373.6	NA, NA	NA, NA	9.3, 9.3
	BLQ Values Included	0	0	0	1	1	2
Week 2	N	3	3	6		2	2
	MEAN, GEO MEAN	4013.5, 3366.0	1742.3, 1662.4	2877.9, 2365.5		27.7, 20.7	27.7, 20.7
	SD, SE	2738.64, 1581.16	648.77, 374.57	2171.62, 886.56		25.95, 18.35	25.95, 18.35
	MEDIAN	3518.6	1648.3	2040.6		27.7	27.7
	MIN, MAX	1556.0, 6965.8	1145.6, 2432.9	1145.6, 6965.8		9.3, 46.0	9.3, 46.0
	5%, 95%	1556.0, 6965.8	1145.6, 2432.9	1145.6, 6965.8		9.3, 46.0	9.3, 46.0
	BLQ Values Included	0	0	0		2	2
Week 3	N	2	3	5	2	2	4
	MEAN, GEO MEAN	2136.0, 1288.9	1660.5, 1587.1	1850.7, 1460.3	9.3, 9.3	9.3, 9.3	9.3, 9.3
	SD, SE	2408.76, 1703.25	640.98, 370.07	1312.92, 587.16	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	2136.0	1299.6	1299.6	9.3	9.3	9.3
	MIN, MAX	432.7, 3839.2	1281.4, 2400.6	432.7, 3839.2	9.3, 9.3	9.3, 9.3	9.3, 9.3
	5%, 95%	432.7, 3839.2	1281.4, 2400.6	432.7, 3839.2	9.3, 9.3	9.3, 9.3	9.3, 9.3
	BLQ Values Included	0	0	0	2	2	4
Overall*	N	3	3	6	3	3	6
	MEAN, GEO MEAN	3325.3, 2421.6	1665.5, 1590.4	2495.4, 1962.5	9.3, 9.3	13.4, 12.3	11.3, 10.7
	SD, SE	2836.52, 1637.67	639.69, 369.33	2051.46, 837.50	0.00, 0.00	7.04, 4.07	4.98, 2.03
	MEDIAN	2785.6	1426.6	1908.5	9.3	9.3	9.3
	MIN, MAX	797.4, 6392.9	1179.7, 2390.3	797.4, 6392.9	9.3, 9.3	9.3, 21.5	9.3, 21.5
	5%, 95%	797.4, 6392.9	1179.7, 2390.3	797.4, 6392.9	9.3, 9.3	9.3, 21.5	9.3, 21.5

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Nicotine Glucuronide (nmol/24hr)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	1	1	2
	MEAN, GEO MEAN	3712.730, 2363.770	3729.770, 3457.330	3721.250, 2858.730	27.900, 27.900	11.160, 11.160	19.530, 17.646
	SD, SE	3386.7000, 1955.3100	1798.4400, 1038.3300	2425.2300, 990.0960	NA, NA	NA, NA	11.8370, 8.3700
	MEDIAN	3304.530	3225.090	3264.810	27.900	11.160	19.530
	MIN, MAX	548.624, 7285.032	2237.592, 5726.630	548.624, 7285.032	27.900, 27.900	11.160, 11.160	11.160, 27.900
	5%, 95%	548.624, 7285.030	2237.590, 5726.630	548.624, 7285.030	NA, NA	NA, NA	11.160, 27.900
	BLQ Values Included	0	0	0	1	1	2
Week 2	N	3	3	6		2	2
	MEAN, GEO MEAN	4306.240, 4043.740	4015.240, 3928.440	4160.740, 3985.670		39.730, 38.893	39.730, 38.893
	SD, SE	1923.8500, 1110.7300	1062.4300, 613.3960	1399.0600, 571.1660		11.4693, 8.1100	11.4693, 8.1100
	MEDIAN	3624.160	3551.360	3587.760		39.730	39.730
	MIN, MAX	2816.360, 6478.194	3263.634, 5230.735	2816.360, 6478.194		31.620, 47.840	31.620, 47.840
	5%, 95%	2816.360, 6478.190	3263.630, 5230.740	2816.360, 6478.190		31.620, 47.840	31.620, 47.840
	BLQ Values Included	0	0	0		2	2
Week 3	N	2	3	5	2	2	4
	MEAN, GEO MEAN	3273.940, 1885.030	3447.030, 3209.520	3377.800, 2594.130	17.968, 17.926	20.739, 18.674	19.353, 18.296
	SD, SE	3785.5900, 2676.8200	1583.0300, 913.9650	2201.0600, 984.3430	1.7359, 1.2275	12.7576, 9.0210	7.6038, 3.8019
	MEDIAN	3273.940	3139.430	3139.430	17.968	20.739	17.968
	MIN, MAX	597.126, 5950.760	2040.372, 5161.290	597.126, 5950.760	16.740, 19.195	11.718, 29.760	11.718, 29.760
	5%, 95%	597.126, 5950.760	2040.370, 5161.290	597.126, 5950.760	16.740, 19.195	11.718, 29.760	11.718, 29.760
	BLQ Values Included	0	0	0	2	2	4
Overall*	N	3	3	6	3	3	6
	MEAN, GEO MEAN	3785.460, 3109.510	3730.680, 3547.480	3758.070, 3321.290	21.278, 20.774	28.318, 28.098	24.798, 24.160
	SD, SE	2640.0000, 1524.2100	1476.2200, 852.2950	1913.2300, 781.0710	5.8644, 3.3858	4.2129, 2.4323	5.9768, 2.4400
	MEDIAN	3464.340	3305.290	3384.820	19.195	29.760	25.737
	MIN, MAX	1320.700, 6571.330	2513.870, 5372.890	1320.700, 6571.330	16.740, 27.900	23.573, 31.620	16.740, 31.620
	5%, 95%	1320.700, 6571.330	2513.870, 5372.890	1320.700, 6571.330	16.740, 27.900	23.573, 31.620	16.740, 31.620

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Nicotine Glucuronide (nmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	1	1	2
	MEAN, GEO MEAN	2.478, 1.628	3.022, 2.636	2.750, 2.071	0.011, 0.011	0.014, 0.014	0.013, 0.012
	SD, SE	2.3928, 1.3815	1.6021, 0.9250	1.8455, 0.7534	NA, NA	NA, NA	0.0021, 0.0015
	MEDIAN	1.864	3.809	2.837	0.011	0.014	0.013
	MIN, MAX	0.452, 5.118	1.179, 4.079	0.452, 5.118	0.011, 0.011	0.014, 0.014	0.011, 0.014
	5%, 95%	0.452, 5.118	1.179, 4.079	0.452, 5.118	NA, NA	NA, NA	0.011, 0.014
	BLQ Values Included	0	0	0	1	1	2
Week 2	N	3	3	6		2	2
	MEAN, GEO MEAN	3.716, 3.439	2.965, 2.868	3.341, 3.141		0.036, 0.036	0.036, 0.036
	SD, SE	1.8604, 1.0741	0.8736, 0.5044	1.3634, 0.5566		0.0042, 0.0030	0.0042, 0.0030
	MEDIAN	2.941	3.310	3.126		0.036	0.036
	MIN, MAX	2.369, 5.839	1.972, 3.614	1.972, 5.839		0.033, 0.039	0.033, 0.039
	5%, 95%	2.369, 5.839	1.972, 3.614	1.972, 5.839		0.033, 0.039	0.033, 0.039
	BLQ Values Included	0	0	0		2	2
Week 3	N	2	3	5	2	2	4
	MEAN, GEO MEAN	2.936, 2.263	3.107, 2.733	3.039, 2.535	0.015, 0.014	0.015, 0.014	0.015, 0.014
	SD, SE	2.6439, 1.8695	1.7805, 1.0280	1.8280, 0.8175	0.0057, 0.0040	0.0085, 0.0060	0.0059, 0.0029
	MEDIAN	2.936	3.022	3.022	0.015	0.015	0.015
	MIN, MAX	1.066, 4.805	1.371, 4.929	1.066, 4.929	0.011, 0.019	0.009, 0.021	0.009, 0.021
	5%, 95%	1.066, 4.805	1.371, 4.929	1.066, 4.929	0.011, 0.019	0.009, 0.021	0.009, 0.021
	BLQ Values Included	0	0	0	2	2	4
Overall*	N	3	3	6	3	3	6
	MEAN, GEO MEAN	2.952, 2.547	3.032, 2.783	2.992, 2.662	0.014, 0.013	0.025, 0.024	0.019, 0.018
	SD, SE	2.0181, 1.1652	1.3568, 0.7833	1.5386, 0.6281	0.0046, 0.0027	0.0069, 0.0040	0.0081, 0.0033
	MEDIAN	2.117	3.482	2.800	0.011	0.021	0.020
	MIN, MAX	1.486, 5.254	1.507, 4.106	1.486, 5.254	0.011, 0.019	0.021, 0.033	0.011, 0.033
	5%, 95%	1.486, 5.254	1.507, 4.106	1.486, 5.254	0.011, 0.019	0.021, 0.033	0.011, 0.033

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., <1.234 will be used as 1.234) for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Cotinine Glucuronide (nmol/24hr)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	3	2	5
	MEAN, GEO MEAN	13071.900, 6498.190	13773.200, 13119.300	13422.600, 9233.170	17.169, 16.468	17.412, 15.500	17.266, 16.074
	SD, SE	11737.1000, 6776.4200	5506.3000, 3179.0700	8208.4800, 3351.1000	6.0729, 3.5062	11.2168, 7.9315	7.0648, 3.1595
	MEDIAN	14233.800	10987.200	12610.500	16.116	17.412	16.116
	MIN, MAX	797.096, 24184.869	10216.584, 20115.725	797.096, 24184.869	11.692, 23.700	9.480, 25.343	9.480, 25.343
	5%, 95%	797.096, 24184.900	10216.600, 20115.700	797.096, 24184.900	11.692, 23.700	9.480, 25.343	9.480, 25.343
Week 2	BLQ Values Included	0	0	0	3	2	5
	N	3	3	6	4	3	7
	MEAN, GEO MEAN	12636.600, 8989.660	13934.500, 13447.500	13285.500, 10994.900	17.795, 17.207	19.263, 17.114	18.424, 17.167
	SD, SE	9131.5200, 5272.0800	4577.3700, 2642.7400	6499.2400, 2653.3000	5.2448, 2.6224	9.7891, 5.6517	6.8053, 2.5722
	MEDIAN	15906.200	13037.400	14471.800	17.499	22.713	21.725
	MIN, MAX	2320.420, 19683.264	9872.082, 18893.985	2320.420, 19683.264	13.272, 22.910	8.216, 26.860	8.216, 26.860
Week 3	5%, 95%	2320.420, 19683.300	9872.080, 18894.000	2320.420, 19683.300	13.272, 22.910	8.216, 26.860	8.216, 26.860
	BLQ Values Included	0	0	0	4	3	7
	N	2	3	5	3	3	6
	MEAN, GEO MEAN	9852.460, 2562.480	11811.600, 11287.300	11027.900, 6237.610	17.812, 17.448	12.140, 11.974	14.976, 14.454
	SD, SE	13454.0000, 9513.3900	4052.3300, 2339.6200	7390.1600, 3304.9800	4.5365, 2.6192	2.4911, 1.4382	4.5130, 1.8424
	MEDIAN	9852.460	12845.600	12845.600	16.306	11.613	14.536
Overall*	MIN, MAX	339.066, 19365.855	7342.419, 15246.725	339.066, 19365.855	14.220, 22.910	9.954, 14.852	9.954, 22.910
	5%, 95%	339.066, 19365.900	7342.420, 15246.700	339.066, 19365.900	14.220, 22.910	9.954, 14.852	9.954, 22.910
	BLQ Values Included	0	0	0	3	3	6
	N	3	3	6	4	4	8
	MEAN, GEO MEAN	12433.400, 7153.010	13173.100, 12666.900	12803.200, 9518.730	17.802, 17.491	16.429, 15.218	17.115, 16.315
	SD, SE	10221.2000, 5901.2200	4535.8300, 2618.7600	7083.9900, 2892.0300	3.9046, 1.9523	7.1309, 3.5655	5.3727, 1.8995
Overall*	MEDIAN	15070.000	12290.100	13680.100	16.980	16.235	16.980
	MIN, MAX	1152.190, 21078.000	9143.700, 18085.500	1152.190, 21078.000	14.536, 22.713	9.217, 24.028	9.217, 24.028
	5%, 95%	1152.190, 21078.000	9143.700, 18085.500	1152.190, 21078.000	14.536, 22.713	9.217, 24.028	9.217, 24.028

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Cotinine Glucuronide (nmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	3	2	5
	MEAN, GEO MEAN	8.559, 4.473	10.895, 10.002	9.727, 6.689	0.009, 0.009	0.019, 0.017	0.013, 0.012
	SD, SE	8.1809, 4.7232	4.8224, 2.7842	6.1408, 2.5070	0.0025, 0.0015	0.0092, 0.0065	0.0070, 0.0031
	MEDIAN	8.030	12.975	10.503	0.009	0.019	0.012
	MIN, MAX	0.656, 16.992	5.382, 14.329	0.656, 16.992	0.007, 0.012	0.012, 0.025	0.007, 0.025
	5%, 95%	0.656, 16.992	5.382, 14.329	0.656, 16.992	0.007, 0.012	0.012, 0.025	0.007, 0.025
	BLQ Values Included	0	0	0	3	2	5
Week 2	N	3	3	6	4	3	7
	MEAN, GEO MEAN	10.188, 7.646	10.396, 9.817	10.292, 8.664	0.010, 0.009	0.017, 0.015	0.013, 0.011
	SD, SE	7.6612, 4.4232	3.8935, 2.2479	5.4364, 2.2194	0.0045, 0.0023	0.0105, 0.0061	0.0079, 0.0030
	MEDIAN	10.399	11.956	11.178	0.010	0.017	0.010
	MIN, MAX	2.423, 17.741	5.964, 13.267	2.423, 17.741	0.005, 0.016	0.007, 0.028	0.005, 0.028
	5%, 95%	2.423, 17.741	5.964, 13.267	2.423, 17.741	0.005, 0.016	0.007, 0.028	0.005, 0.028
	BLQ Values Included	0	0	0	4	3	7
Week 3	N	2	3	5	3	3	6
	MEAN, GEO MEAN	8.121, 3.076	10.620, 9.613	9.621, 6.094	0.013, 0.013	0.013, 0.012	0.013, 0.013
	SD, SE	10.6292, 7.5160	5.0463, 2.9135	6.5461, 2.9275	0.0038, 0.0022	0.0044, 0.0025	0.0037, 0.0015
	MEDIAN	8.121	12.366	12.366	0.015	0.015	0.015
	MIN, MAX	0.605, 15.637	4.933, 14.562	0.605, 15.637	0.009, 0.016	0.008, 0.016	0.008, 0.016
	5%, 95%	0.605, 15.637	4.933, 14.562	0.605, 15.637	0.009, 0.016	0.008, 0.016	0.008, 0.016
	BLQ Values Included	0	0	0	3	3	6
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	9.078, 5.749	10.637, 9.833	9.857, 7.519	0.011, 0.010	0.017, 0.016	0.014, 0.013
	SD, SE	7.7819, 4.4929	4.5283, 2.6144	5.7580, 2.3507	0.0026, 0.0013	0.0059, 0.0030	0.0055, 0.0019
	MEDIAN	9.215	12.869	11.042	0.011	0.019	0.013
	MIN, MAX	1.228, 16.790	5.426, 13.616	1.228, 16.790	0.007, 0.013	0.009, 0.022	0.007, 0.022
	5%, 95%	1.228, 16.790	5.426, 13.616	1.228, 16.790	0.007, 0.013	0.009, 0.022	0.007, 0.022

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., <1.234* will be used as 1.234*) for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Cotinine Glucuronide (nmol/L)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	3	2	5
	MEAN, GEO MEAN	12408.6, 5242.0	6026.8, 5740.5	9217.7, 5485.6	7.9, 7.9	7.9, 7.9	7.9, 7.9
	SD, SE	13952.70, 8055.59	2211.40, 1276.75	9594.01, 3916.74	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	8840.9	6081.3	7145.9	7.9	7.9	7.9
	MIN, MAX	586.1, 27798.7	3788.7, 8210.5	586.1, 27798.7	7.9, 7.9	7.9, 7.9	7.9, 7.9
	5%, 95%	586.1, 27798.7	3788.7, 8210.5	586.1, 27798.7	7.9, 7.9	7.9, 7.9	7.9, 7.9
	BLQ Values Included	0	0	0	3	2	5
Week 2	N	3	3	6	4	3	7
	MEAN, GEO MEAN	12629.9, 7483.0	5993.1, 5690.5	9311.5, 6525.5	7.9, 7.9	7.9, 7.9	7.9, 7.9
	SD, SE	10235.50, 5909.49	2451.58, 1415.42	7584.50, 3096.36	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	15442.9	4985.9	6886.9	7.9	7.9	7.9
	MIN, MAX	1282.0, 21164.8	4205.6, 8787.9	1282.0, 21164.8	7.9, 7.9	7.9, 7.9	7.9, 7.9
	5%, 95%	1282.0, 21164.8	4205.6, 8787.9	1282.0, 21164.8	7.9, 7.9	7.9, 7.9	7.9, 7.9
	BLQ Values Included	0	0	0	4	3	7
Week 3	N	2	3	5	3	3	6
	MEAN, GEO MEAN	6369.9, 1752.1	5670.4, 5581.6	5950.2, 3511.4	7.9, 7.9	7.9, 7.9	7.9, 7.9
	SD, SE	8660.93, 6124.20	1262.84, 729.10	4438.14, 1984.80	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	6369.9	5243.1	5243.1	7.9	7.9	7.9
	MIN, MAX	245.7, 12494.1	4676.7, 7091.5	245.7, 12494.1	7.9, 7.9	7.9, 7.9	7.9, 7.9
	5%, 95%	245.7, 12494.1	4676.7, 7091.5	245.7, 12494.1	7.9, 7.9	7.9, 7.9	7.9, 7.9
	BLQ Values Included	0	0	0	3	3	6
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	11110.8, 5596.2	5896.8, 5707.7	8503.8, 5651.7	7.9, 7.9	7.9, 7.9	7.9, 7.9
	SD, SE	9930.88, 5733.59	1894.02, 1093.51	7002.82, 2858.89	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	12141.9	5248.0	6639.0	7.9	7.9	7.9
	MIN, MAX	704.6, 20485.9	4412.5, 8030.0	704.6, 20485.9	7.9, 7.9	7.9, 7.9	7.9, 7.9
	5%, 95%	704.6, 20485.9	4412.5, 8030.0	704.6, 20485.9	7.9, 7.9	7.9, 7.9	7.9, 7.9

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: 3-hydroxycotinine glucuronide (nmol/L)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	1	1	2
	MEAN, GEO MEAN	2967.6, 2577.2	3491.0, 3364.4	3229.3, 2944.6	12.6, 12.6	23.5, 23.5	18.1, 17.2
	SD, SE	1587.37, 916.47	1069.44, 617.44	1244.01, 507.87	NA, NA	NA, NA	7.71, 5.45
	MEDIAN	3869.9	4093.9	3884.0	12.6	23.5	18.1
	MIN, MAX	1134.7, 3898.1	2256.2, 4122.8	1134.7, 4122.8	12.6, 12.6	23.5, 23.5	12.6, 23.5
	5%, 95%	1134.7, 3898.1	2256.2, 4122.8	1134.7, 4122.8	NA, NA	NA, NA	12.6, 23.5
	BLQ Values Included	0	0	0	0	0	0
Week 2	N	3	3	6	1		1
	MEAN, GEO MEAN	5047.3, 4630.8	2475.6, 2404.6	3761.5, 3336.9	14.3, 14.3		14.3, 14.3
	SD, SE	2322.19, 1340.72	758.18, 437.73	2090.68, 853.52	NA, NA		NA, NA
	MEDIAN	5439.6	2146.2	2948.4	14.3		14.3
	MIN, MAX	2553.9, 7148.3	1937.9, 3342.8	1937.9, 7148.3	14.3, 14.3		14.3, 14.3
	5%, 95%	2553.9, 7148.3	1937.9, 3342.8	1937.9, 7148.3	NA, NA		NA, NA
	BLQ Values Included	0	0	0	0		0
Week 3	N	2	3	5			
	MEAN, GEO MEAN	1746.4, 932.8	2906.2, 1703.6	2442.3, 1338.9			
	SD, SE	2087.94, 1476.40	3474.95, 2006.26	2744.27, 1227.28			
	MEDIAN	1746.4	1240.5	1240.5			
	MIN, MAX	270.0, 3222.8	577.6, 6900.4	270.0, 6900.4			
	5%, 95%	270.0, 3222.8	577.6, 6900.4	270.0, 6900.4			
	BLQ Values Included	0	0	0			
Overall*	N	3	3	6	1	1	2
	MEAN, GEO MEAN	3671.8, 3122.2	2957.6, 2709.5	3314.7, 2908.5	13.5, 13.5	23.5, 23.5	18.5, 17.8
	SD, SE	2141.75, 1236.54	1586.08, 915.72	1730.35, 706.41	NA, NA	NA, NA	7.07, 5.00
	MEDIAN	4186.8	2212.8	3199.8	13.5	23.5	18.5
	MIN, MAX	1319.5, 5509.1	1881.0, 4779.0	1319.5, 5509.1	13.5, 13.5	23.5, 23.5	13.5, 23.5
	5%, 95%	1319.5, 5509.1	1881.0, 4779.0	1319.5, 5509.1	NA, NA	NA, NA	13.5, 23.5

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL.
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Biomarker: 3-hydroxycotinine glucuronide (nmol/24hr)

Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	1	1	2
	MEAN, GEO MEAN	3721.690, 3194.770	8108.770, 7688.830	5915.230, 4956.210	16.758, 16.758	76.375, 76.375	46.567, 35.776
	SD, SE	2361.0700, 1363.1600	3333.5000, 1924.6000	3528.2700, 1440.4100	NA, NA	NA, NA	42.1556, 29.8085
	MEDIAN	3391.350	6926.300	5879.110	16.758	76.375	46.567
	MIN, MAX	1543.192, 6230.539	5527.690, 11872.310	1543.192, 11872.310	16.758, 16.758	76.375, 76.375	16.758, 76.375
	5%, 95%	1543.190, 6230.540	5527.690, 11872.300	1543.190, 11872.300	NA, NA	NA, NA	16.758, 76.375
	BLQ Values Included	0	0	0	0	0	0
Week 2	N	3	3	6	1		1
	MEAN, GEO MEAN	5681.380, 5563.190	6271.350, 5682.320	5976.360, 5622.440	24.024, 24.024		24.024, 24.024
	SD, SE	1472.3600, 850.0660	3564.4500, 2057.9300	2460.4200, 1004.4600	NA, NA		NA, NA
	MEDIAN	5058.830	4614.330	4840.690	24.024		24.024
	MIN, MAX	4622.559, 7362.749	3837.042, 10362.680	3837.042, 10362.680	24.024, 24.024		24.024, 24.024
	5%, 95%	4622.560, 7362.750	3837.040, 10362.700	3837.040, 10362.700	NA, NA		NA, NA
	BLQ Values Included	0	0	0	0		0
Week 3	N	2	3	5			
	MEAN, GEO MEAN	2683.970, 1364.280	6826.630, 3445.090	5169.570, 2378.380			
	SD, SE	3268.7700, 2311.3700	8773.2300, 5065.2300	6804.7400, 3043.1700			
	MEDIAN	2683.970	2667.080	2667.080			
	MIN, MAX	372.600, 4995.340	906.832, 16905.980	372.600, 16905.980			
	5%, 95%	372.600, 4995.340	906.832, 16906.000	372.600, 16906.000			
	BLQ Values Included	0	0	0			
Overall*	N	3	3	6	1	1	2
	MEAN, GEO MEAN	4485.980, 4049.170	7068.920, 6006.500	5777.450, 4931.670	20.391, 20.391	76.375, 76.375	48.383, 39.463
	SD, SE	2308.6000, 1332.8700	5180.6500, 2991.0500	3856.0300, 1574.2200	NA, NA	NA, NA	39.5867, 27.9920
	MEDIAN	4481.840	4269.700	4375.770	20.391	76.375	48.383
	MIN, MAX	2179.450, 6796.640	3890.060, 13047.000	2179.450, 13047.000	20.391, 20.391	76.375, 76.375	20.391, 76.375
	5%, 95%	2179.450, 6796.640	3890.060, 13047.000	2179.450, 13047.000	NA, NA	NA, NA	20.391, 76.375
	BLQ Values Included						

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: 3-hydroxycotinine glucuronide (nmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	1	1	2
	MEAN, GEO MEAN	2.390, 2.200	7.202, 5.862	4.796, 3.591	0.007, 0.007	0.055, 0.055	0.031, 0.020
	SD, SE	1.1220, 0.6478	5.9063, 3.4100	4.6266, 1.8888	NA, NA	NA, NA	0.0339, 0.0240
	MEDIAN	2.383	3.938	3.582	0.007	0.055	0.031
	MIN, MAX	1.271, 3.515	3.648, 14.020	1.271, 14.020	0.007, 0.007	0.055, 0.055	0.007, 0.055
	5%, 95%	1.271, 3.515	3.648, 14.020	1.271, 14.020	NA, NA	NA, NA	0.007, 0.055
	BLQ Values Included	0	0	0	0	0	0
Week 2	N	3	3	6	1		1
	MEAN, GEO MEAN	4.734, 4.732	5.261, 4.148	4.998, 4.431	0.009, 0.009		0.009, 0.009
	SD, SE	0.1509, 0.0871	4.5860, 2.6477	2.9163, 1.1906	NA, NA		NA, NA
	MEDIAN	4.814	2.920	4.687	0.009		0.009
	MIN, MAX	4.560, 4.828	2.318, 10.545	2.318, 10.545	0.009, 0.009		0.009, 0.009
	5%, 95%	4.560, 4.828	2.318, 10.545	2.318, 10.545	NA, NA		NA, NA
	BLQ Values Included	0	0	0	0		0
Week 3	N	2	3	5			
	MEAN, GEO MEAN	2.350, 1.638	6.477, 2.934	4.826, 2.324			
	SD, SE	2.3822, 1.6845	8.5405, 4.9308	6.5574, 2.9326			
	MEDIAN	2.350	2.547	2.547			
	MIN, MAX	0.665, 4.034	0.609, 16.275	0.609, 16.275			
	5%, 95%	0.665, 4.034	0.609, 16.275	0.609, 16.275			
	BLQ Values Included	0	0	0			
Overall*	N	3	3	6	1	1	2
	MEAN, GEO MEAN	3.360, 3.251	6.313, 4.540	4.837, 3.842	0.008, 0.008	0.055, 0.055	0.032, 0.021
	SD, SE	0.9896, 0.5713	6.3393, 3.6600	4.3685, 1.7834	NA, NA	NA, NA	0.0332, 0.0235
	MEDIAN	3.659	3.135	3.397	0.008	0.055	0.032
	MIN, MAX	2.255, 4.165	2.192, 13.613	2.192, 13.613	0.008, 0.008	0.055, 0.055	0.008, 0.055
	5%, 95%	2.255, 4.165	2.192, 13.613	2.192, 13.613	NA, NA	NA, NA	0.008, 0.055

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total NNAL (pg/mL)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	17	32	49	30	36	66
	MEAN, GEO MEAN	532.4, 308.3	554.4, 360.2	546.8, 341.2	13.7, 7.5	6.0, 6.0	9.5, 6.7
	SD, SE	500.33, 121.35	459.48, 81.23	468.94, 66.99	33.35, 6.09	0.17, 0.03	22.61, 2.78
	MEDIAN	445.5	484.0	475.2	6.0	6.0	6.0
	MIN, MAX	6.0, 1773.9	13.5, 2045.7	6.0, 2045.7	6.0, 185.7	6.0, 7.0	6.0, 185.7
	5%, 95%	6.0, 1773.9	16.5, 1604.2	16.5, 1604.2	6.0, 47.3	6.0, 6.0	6.0, 8.8
	BLQ Values Included	1	0	1	24	35	59
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	427.5, 286.6	626.3, 425.9	552.8, 367.9	7.5, 6.6	7.2, 6.6	7.4, 6.6
	SD, SE	313.45, 76.02	557.17, 103.46	487.35, 71.86	7.53, 1.38	4.68, 0.78	6.09, 0.75
	MEDIAN	415.9	482.0	426.6	6.0	6.0	6.0
	MIN, MAX	6.0, 1235.3	30.5, 2223.3	6.0, 2223.3	6.0, 47.3	6.0, 31.4	6.0, 47.3
	5%, 95%	6.0, 1235.3	53.0, 1842.9	53.0, 1721.9	6.0, 8.6	6.0, 17.7	6.0, 11.9
	BLQ Values Included	1	0	1	26	33	59
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	486.9, 321.5	573.7, 393.7	542.5, 366.0	10.6, 7.3	6.6, 6.4	8.4, 6.8
	SD, SE	362.20, 85.37	462.07, 81.68	427.04, 60.39	17.77, 3.24	2.34, 0.39	12.16, 1.50
	MEDIAN	385.6	453.3	433.9	6.0	6.0	6.0
	MIN, MAX	6.0, 1230.7	22.0, 1663.1	6.0, 1663.1	6.0, 95.9	6.0, 18.7	6.0, 95.9
	5%, 95%	6.0, 1230.7	34.8, 1653.7	34.8, 1471.5	6.0, 47.3	6.0, 11.9	6.0, 11.9

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total NNAL (pmol/L)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	17	32	49	30	36	66
	MEAN, GEO MEAN	2544.7, 1473.7	2650.1, 1721.5	2613.5, 1631.1	65.3, 35.9	28.8, 28.8	45.4, 31.8
	SD, SE	2391.57, 580.04	2196.31, 388.26	2241.53, 320.22	159.42, 29.11	0.80, 0.13	108.05, 13.30
	MEDIAN	2129.5	2313.3	2271.5	28.7	28.7	28.7
	MIN, MAX	28.7, 8479.2	64.5, 9778.4	28.7, 9778.4	28.7, 887.6	28.7, 33.5	28.7, 887.6
	5%, 95%	28.7, 8479.2	78.9, 7668.1	78.9, 7668.1	28.7, 226.1	28.7, 28.7	28.7, 42.1
	BLQ Values Included	1	0	1	24	35	59
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	2043.4, 1370.0	2993.7, 2035.8	2642.5, 1758.6	36.1, 31.5	34.4, 31.6	35.2, 31.5
	SD, SE	1498.29, 363.39	2663.28, 494.56	2329.54, 343.47	36.01, 6.57	22.35, 3.73	29.12, 3.58
	MEDIAN	1988.0	2304.0	2038.9	28.7	28.7	28.7
	MIN, MAX	28.7, 5904.7	145.8, 10627.4	28.7, 10627.4	28.7, 226.1	28.7, 150.1	28.7, 226.1
	5%, 95%	28.7, 5904.7	253.3, 8809.1	253.3, 8230.7	28.7, 41.1	28.7, 84.6	28.7, 56.9
	BLQ Values Included	1	0	1	26	33	59
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	2327.4, 1536.6	2742.2, 1881.7	2592.9, 1749.4	50.7, 34.9	31.6, 30.6	40.3, 32.5
	SD, SE	1731.30, 408.07	2208.67, 390.44	2041.22, 288.67	84.92, 15.50	11.17, 1.86	58.10, 7.15
	MEDIAN	1843.1	2166.6	2074.0	28.7	28.7	28.7
	MIN, MAX	28.7, 5882.5	105.2, 7949.4	28.7, 7949.4	28.7, 458.2	28.7, 89.4	28.7, 458.2
	5%, 95%	28.7, 5882.5	166.1, 7904.4	166.1, 7033.6	28.7, 226.1	28.7, 56.7	28.7, 56.7

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free NNAL (pg/mL)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	121.7, 84.9	166.0, 120.8	150.0, 106.4	6.5, 6.2	6.3, 6.2	6.4, 6.2
	SD, SE	83.64, 19.71	116.66, 20.62	107.23, 15.16	2.61, 0.48	0.92, 0.15	1.87, 0.23
	MEDIAN	127.5	150.8	136.4	6.0	6.0	6.0
	MIN, MAX	6.0, 333.0	6.0, 484.5	6.0, 484.5	6.0, 20.3	6.0, 9.6	6.0, 20.3
	5%, 95%	6.0, 333.0	11.4, 463.9	11.4, 347.9	6.0, 6.0	6.0, 9.6	6.0, 8.5
	BLQ Values Included	1	1	2	29	33	62
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	122.7, 89.1	183.8, 149.5	161.2, 123.5	8.7, 7.1	6.1, 6.1	7.3, 6.5
	SD, SE	81.19, 19.69	118.10, 21.93	109.14, 16.09	9.14, 1.67	0.75, 0.13	6.26, 0.77
	MEDIAN	134.6	160.8	144.2	6.0	6.0	6.0
	MIN, MAX	6.0, 290.8	28.2, 485.1	6.0, 485.1	6.0, 42.4	6.0, 10.5	6.0, 42.4
	5%, 95%	6.0, 290.8	45.6, 411.9	28.2, 405.1	6.0, 40.7	6.0, 6.0	6.0, 10.5
	BLQ Values Included	1	0	1	27	35	62
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	122.7, 92.8	171.2, 135.6	153.7, 118.3	7.6, 6.9	6.2, 6.2	6.8, 6.5
	SD, SE	68.42, 16.13	112.66, 19.92	101.02, 14.29	4.69, 0.86	0.59, 0.10	3.24, 0.40
	MEDIAN	135.9	152.1	138.9	6.0	6.0	6.0
	MIN, MAX	6.0, 233.8	17.1, 474.5	6.0, 474.5	6.0, 24.2	6.0, 8.3	6.0, 24.2
	5%, 95%	6.0, 233.8	28.5, 444.8	20.9, 351.6	6.0, 23.4	6.0, 7.8	6.0, 11.4

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234' for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free NNAL (pmol/L)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	581.6, 405.8	793.5, 577.7	717.2, 508.7	31.0, 29.9	30.0, 29.7	30.4, 29.8
	SD, SE	399.78, 94.23	557.62, 98.57	512.56, 72.49	12.47, 2.28	4.39, 0.73	8.94, 1.10
	MEDIAN	609.5	720.6	652.0	28.7	28.7	28.7
	MIN, MAX	28.7, 1591.7	28.7, 2315.9	28.7, 2315.9	28.7, 97.0	28.7, 45.9	28.7, 97.0
	5%, 95%	28.7, 1591.7	54.5, 2217.4	54.5, 1663.0	28.7, 28.7	28.7, 45.9	28.7, 40.6
	BLQ Values Included	1	1	2	29	33	62
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	586.3, 426.0	878.5, 714.7	770.5, 590.3	41.7, 33.8	29.3, 29.1	34.9, 31.2
	SD, SE	388.07, 94.12	564.50, 104.82	521.68, 76.92	43.66, 7.97	3.58, 0.60	29.94, 3.69
	MEDIAN	643.4	768.6	689.0	28.7	28.7	28.7
	MIN, MAX	28.7, 1390.0	134.8, 2318.8	28.7, 2318.8	28.7, 202.7	28.7, 50.2	28.7, 202.7
	5%, 95%	28.7, 1390.0	218.0, 1968.9	134.8, 1936.4	28.7, 194.5	28.7, 28.7	28.7, 50.2
	BLQ Values Included	1	0	1	27	35	62
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	586.6, 443.3	818.0, 648.1	734.7, 565.3	36.4, 33.0	29.6, 29.5	32.7, 31.1
	SD, SE	327.02, 77.08	538.54, 95.20	482.89, 68.29	22.37, 4.08	2.77, 0.46	15.45, 1.90
	MEDIAN	649.5	726.7	663.9	28.7	28.7	28.7
	MIN, MAX	28.7, 1117.6	81.8, 2268.1	28.7, 2268.1	28.7, 115.7	28.7, 39.5	28.7, 115.7
	5%, 95%	28.7, 1117.6	136.3, 2126.2	99.9, 1680.7	28.7, 111.6	28.7, 37.3	28.7, 54.3

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Nicotine (ng/mL)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1588.4, 986.2	1626.2, 879.4	1612.6, 916.5	3.8, 1.9	1.2, 1.1	2.4, 1.4
	SD, SE	1414.79, 333.47	1794.81, 317.28	1653.11, 233.78	6.34, 1.16	0.76, 0.13	4.47, 0.55
	MEDIAN	1284.7	850.1	1000.4	1.0	1.0	1.0
	MIN, MAX	15.7, 5625.0	42.3, 8096.4	15.7, 8096.4	1.0, 23.2	1.0, 5.4	1.0, 23.2
	5%, 95%	15.7, 5625.0	88.4, 5070.3	88.4, 5070.3	1.0, 22.6	1.0, 2.1	1.0, 8.8
	BLQ Values Included	0	0	0	15	29	44
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	1772.2, 1162.4	1807.8, 1057.5	1794.7, 1094.9	5.9, 1.7	1.2, 1.1	3.3, 1.3
	SD, SE	1309.83, 308.73	2129.81, 382.53	1855.53, 265.08	22.05, 4.03	0.57, 0.09	14.92, 1.84
	MEDIAN	1350.6	1096.3	1304.2	1.0	1.0	1.0
	MIN, MAX	11.9, 5120.6	103.2, 10733.1	11.9, 10733.1	1.0, 122.3	1.0, 3.6	1.0, 122.3
	5%, 95%	11.9, 5120.6	151.2, 6116.5	151.2, 5120.6	1.0, 6.8	1.0, 2.8	1.0, 5.1
	BLQ Values Included	0	0	0	19	32	51
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	1439.8, 874.6	1711.5, 1202.2	1611.1, 1068.8	1.9, 1.4	1.1, 1.0	1.4, 1.2
	SD, SE	1095.85, 265.78	1316.61, 244.49	1234.16, 181.97	2.69, 0.49	0.20, 0.03	1.86, 0.23
	MEDIAN	939.3	1317.5	1301.9	1.0	1.0	1.0
	MIN, MAX	9.6, 3515.6	51.2, 4831.6	9.6, 4831.6	1.0, 15.2	1.0, 2.1	1.0, 15.2
	5%, 95%	9.6, 3515.6	300.0, 4652.5	253.9, 3911.0	1.0, 5.9	1.0, 1.4	1.0, 2.1
	BLQ Values Included	0	0	0	19	33	52
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1619.5, 1090.0	1662.2, 1039.5	1646.9, 1057.4	3.9, 1.9	1.1, 1.1	2.4, 1.4
	SD, SE	1100.15, 259.31	1630.41, 288.22	1449.86, 205.04	8.86, 1.62	0.40, 0.07	6.08, 0.75
	MEDIAN	1178.2	1264.1	1216.9	1.1	1.0	1.0
	MIN, MAX	12.4, 3783.9	81.6, 7887.0	12.4, 7887.0	1.0, 48.6	1.0, 3.0	1.0, 48.6
	5%, 95%	12.4, 3783.9	163.9, 4037.2	163.9, 3865.6	1.0, 13.0	1.0, 2.0	1.0, 4.5

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234' for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Nicotine (nmol/L)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	9792.4, 6080.2	10025.6, 5421.7	9941.7, 5650.1	23.7, 11.8	7.5, 6.9	14.8, 8.8
	SD, SE	8722.19, 2055.84	11065.00, 1956.03	10191.40, 1441.28	39.08, 7.14	4.70, 0.78	27.56, 3.39
	MEDIAN	7919.9	5240.6	6167.2	6.2	6.2	6.2
	MIN, MAX	96.8, 34678.1	260.8, 49914.3	96.8, 49914.3	6.2, 143.0	6.2, 33.3	6.2, 143.0
	5%, 95%	96.8, 34678.1	545.0, 31258.4	545.0, 31258.4	6.2, 139.3	6.2, 12.9	6.2, 54.3
	BLQ Values Included	0	0	0	15	29	44
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	10925.7, 7166.2	11145.3, 6519.6	11064.6, 6750.1	36.1, 10.3	7.2, 6.8	20.4, 8.2
	SD, SE	8075.10, 1903.32	13130.30, 2358.27	11439.30, 1634.19	135.96, 24.82	3.49, 0.58	92.00, 11.32
	MEDIAN	8326.5	6758.7	8040.4	6.2	6.2	6.2
	MIN, MAX	73.4, 31568.5	635.2, 66169.6	73.4, 66169.6	6.2, 754.0	6.2, 22.2	6.2, 754.0
	5%, 95%	73.4, 31568.5	932.1, 37708.2	932.1, 31568.5	6.2, 41.9	6.2, 17.3	6.2, 31.4
	BLQ Values Included	0	0	0	19	32	51
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	8876.6, 5391.8	10551.6, 7411.7	9932.6, 6589.5	11.8, 8.7	6.5, 6.4	8.9, 7.4
	SD, SE	6755.88, 1638.54	8116.90, 1507.27	7608.62, 1121.83	16.59, 3.03	1.20, 0.20	11.43, 1.41
	MEDIAN	5790.8	8122.4	8025.9	6.2	6.2	6.2
	MIN, MAX	59.2, 21673.7	315.6, 29786.8	59.2, 29786.8	6.2, 93.7	6.2, 12.9	6.2, 93.7
	5%, 95%	59.2, 21673.7	1849.5, 28682.7	1565.3, 24111.3	6.2, 36.4	6.2, 8.6	6.2, 12.9
	BLQ Values Included	0	0	0	19	33	52
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	9984.2, 6720.3	10247.7, 6408.1	10152.9, 6518.8	23.9, 11.4	7.1, 6.8	14.7, 8.6
	SD, SE	6782.43, 1598.63	10051.50, 1776.88	8938.40, 1264.08	54.66, 9.98	2.45, 0.41	37.52, 4.62
	MEDIAN	7263.5	7793.0	7502.2	6.7	6.2	6.2
	MIN, MAX	76.5, 23327.7	502.8, 48623.6	76.5, 48623.6	6.2, 299.8	6.2, 18.3	6.2, 299.8
	5%, 95%	76.5, 23327.7	1010.2, 24889.6	1010.2, 23831.4	6.2, 79.9	6.2, 12.5	6.2, 28.0

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Cotinine (ng/mL)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	3253.1, 1925.2	3150.1, 2046.6	3187.2, 2002.0	4.5, 2.3	1.8, 1.4	3.0, 1.8
	SD, SE	3277.32, 772.47	2736.60, 483.77	2909.78, 411.50	7.06, 1.29	1.75, 0.29	5.07, 0.62
	MEDIAN	1979.1	2234.6	2020.8	1.5	1.0	1.0
	MIN, MAX	31.6, 12250.5	36.4, 12610.5	31.6, 12610.5	1.0, 35.5	1.0, 7.1	1.0, 35.5
	5%, 95%	31.6, 12250.5	348.7, 8279.7	348.7, 10113.6	1.0, 16.7	1.0, 6.7	1.0, 10.7
	BLQ Values Included	0	0	0	11	23	34
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	3373.5, 2173.6	3802.3, 2490.0	3644.7, 2368.7	5.2, 2.4	1.9, 1.5	3.4, 1.9
	SD, SE	2964.30, 698.69	3672.50, 659.60	3403.71, 486.24	7.93, 1.45	1.51, 0.25	5.66, 0.70
	MEDIAN	2387.9	2731.6	2690.9	1.5	1.0	1.1
	MIN, MAX	28.5, 13012.2	132.0, 18373.7	28.5, 18373.7	1.0, 33.4	1.0, 5.8	1.0, 33.4
	5%, 95%	28.5, 13012.2	503.9, 9222.8	503.9, 9222.8	1.0, 23.2	1.0, 5.5	1.0, 14.1
	BLQ Values Included	0	0	0	12	21	33
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	2794.4, 1791.9	3210.5, 2410.8	3056.7, 2160.4	3.6, 2.1	1.5, 1.3	2.5, 1.6
	SD, SE	1879.15, 455.76	2211.83, 410.73	2083.46, 307.19	6.18, 1.13	1.50, 0.25	4.40, 0.54
	MEDIAN	2377.4	2429.1	2403.3	1.4	1.0	1.0
	MIN, MAX	20.4, 5701.3	279.8, 7919.1	20.4, 7919.1	1.0, 33.8	1.0, 8.8	1.0, 33.8
	5%, 95%	20.4, 5701.3	540.2, 7304.4	390.5, 6761.2	1.0, 11.7	1.0, 4.5	1.0, 6.2
	BLQ Values Included	0	0	0	14	26	40
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	3167.0, 2117.4	3306.6, 2322.6	3256.3, 2246.5	4.4, 2.5	1.7, 1.4	3.0, 1.9
	SD, SE	2358.10, 555.81	2691.91, 475.87	2553.08, 361.06	5.89, 1.07	1.38, 0.23	4.28, 0.53
	MEDIAN	3091.3	2198.6	2699.1	1.8	1.1	1.2
	MIN, MAX	26.8, 9891.3	149.4, 12581.8	26.8, 12581.8	1.0, 27.1	1.0, 6.9	1.0, 27.1
	5%, 95%	26.8, 9891.3	464.3, 7394.7	464.3, 7394.7	1.0, 17.1	1.0, 5.5	1.0, 11.3

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Cotinine (nmol/L)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	18461.1, 10925.4	17876.9, 11614.6	18087.2, 11361.6	25.3, 13.1	10.3, 8.0	17.1, 10.0
	SD, SE	18598.80, 4383.78	15530.20, 2745.38	16513.00, 2335.29	40.09, 7.32	9.95, 1.66	28.76, 3.54
	MEDIAN	11231.4	12681.1	11468.1	8.3	5.7	5.7
	MIN, MAX	179.3, 69521.6	206.6, 71564.6	179.3, 71564.6	5.7, 201.5	5.7, 40.3	5.7, 201.5
	5%, 95%	179.3, 69521.6	1978.9, 46987.3	1978.9, 57394.7	5.7, 94.8	5.7, 38.0	5.7, 60.7
	BLQ Values Included	0	0	0	11	23	34
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	19144.4, 12334.9	21577.8, 14130.7	20683.9, 13442.5	29.5, 13.8	10.7, 8.6	19.2, 10.6
	SD, SE	16822.40, 3965.07	20841.50, 3743.24	19316.10, 2759.44	44.99, 8.21	8.55, 1.43	32.12, 3.95
	MEDIAN	13551.4	15501.8	15270.9	8.5	5.7	6.3
	MIN, MAX	161.7, 73844.2	749.1, 104270.7	161.7, 104270.7	5.7, 189.5	5.7, 32.9	5.7, 189.5
	5%, 95%	161.7, 73844.2	2859.6, 52339.4	2859.6, 52339.4	5.7, 131.7	5.7, 31.2	5.7, 80.0
	BLQ Values Included	0	0	0	12	21	33
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	15858.2, 10169.2	18219.8, 13681.3	17347.0, 12260.6	20.6, 11.8	8.8, 7.2	14.1, 9.0
	SD, SE	10664.20, 2586.44	12552.10, 2330.87	11823.60, 1743.30	35.06, 6.40	8.52, 1.42	24.95, 3.07
	MEDIAN	13491.7	13785.1	13638.4	7.7	5.7	5.7
	MIN, MAX	115.8, 32354.9	1587.9, 44940.9	115.8, 44940.9	5.7, 191.8	5.7, 49.9	5.7, 191.8
	5%, 95%	115.8, 32354.9	3065.6, 41452.5	2216.1, 38369.8	5.7, 66.4	5.7, 25.5	5.7, 35.2
	BLQ Values Included	0	0	0	14	26	40
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	17972.4, 12017.3	18765.0, 13180.7	18479.7, 12749.4	25.1, 14.2	9.9, 8.2	16.8, 10.6
	SD, SE	13382.20, 3154.22	15276.60, 2700.55	14488.80, 2049.02	33.38, 6.09	7.81, 1.30	24.26, 2.99
	MEDIAN	17543.0	12476.8	15317.2	10.3	6.0	6.7
	MIN, MAX	152.3, 56133.3	847.9, 71401.7	152.3, 71401.7	5.7, 153.6	5.7, 39.0	5.7, 153.6
	5%, 95%	152.3, 56133.3	2634.7, 41965.1	2634.7, 41965.1	5.7, 97.2	5.7, 31.0	5.7, 64.0
	BLQ Values Included	0	0	0	0	0	0

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Nicotine (ng/mL)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1071.6, 695.2	1181.3, 590.6	1141.8, 626.3	3.4, 1.7	1.2, 1.1	2.2, 1.3
	SD, SE	894.09, 210.74	1369.23, 242.05	1210.89, 171.25	6.00, 1.10	0.97, 0.16	4.22, 0.52
	MEDIAN	810.1	597.3	649.3	1.0	1.0	1.0
	MIN, MAX	12.8, 3752.0	32.7, 6329.6	12.8, 6329.6	1.0, 24.5	1.0, 6.8	1.0, 24.5
	5%, 95%	12.8, 3752.0	45.8, 3781.9	45.8, 3752.0	1.0, 20.9	1.0, 1.2	1.0, 6.8
	BLQ Values Included	0	0	0	18	34	52
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	1278.9, 872.3	1226.1, 696.3	1245.5, 756.4	5.1, 1.5	1.1, 1.1	2.9, 1.2
	SD, SE	900.59, 212.27	1429.99, 256.83	1251.38, 178.77	19.15, 3.50	0.57, 0.10	12.95, 1.59
	MEDIAN	993.7	730.7	835.4	1.0	1.0	1.0
	MIN, MAX	12.2, 3489.6	67.2, 6634.3	12.2, 6634.3	1.0, 106.2	1.0, 4.3	1.0, 106.2
	5%, 95%	12.2, 3489.6	83.5, 4961.8	83.5, 3489.6	1.0, 5.7	1.0, 2.1	1.0, 4.3
	BLQ Values Included	0	0	0	22	33	55
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	1075.5, 596.6	1220.1, 841.2	1166.7, 740.9	1.5, 1.2	1.0, 1.0	1.2, 1.1
	SD, SE	898.87, 218.01	965.31, 179.25	933.84, 137.69	1.80, 0.33	0.07, 0.01	1.23, 0.15
	MEDIAN	820.2	1123.3	911.3	1.0	1.0	1.0
	MIN, MAX	5.2, 3006.4	30.0, 3630.2	5.2, 3630.2	1.0, 10.5	1.0, 1.4	1.0, 10.5
	5%, 95%	5.2, 3006.4	291.1, 3563.7	131.0, 3006.4	1.0, 4.0	1.0, 1.0	1.0, 1.7
	BLQ Values Included	0	0	0	23	35	58
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1160.2, 803.0	1171.2, 714.3	1167.2, 745.0	3.3, 1.6	1.1, 1.1	2.1, 1.3
	SD, SE	733.75, 172.95	1158.40, 204.78	1017.73, 143.93	7.75, 1.41	0.42, 0.07	5.30, 0.65
	MEDIAN	947.1	705.4	815.5	1.0	1.0	1.0
	MIN, MAX	10.1, 2449.9	65.6, 5531.4	10.1, 5531.4	1.0, 42.7	1.0, 3.3	1.0, 42.7
	5%, 95%	10.1, 2449.9	69.4, 3012.0	69.4, 2950.7	1.0, 9.9	1.0, 2.1	1.0, 3.3

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Nicotine (nmol/L)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	6606.6, 4285.8	7282.7, 3641.2	7039.3, 3861.3	20.9, 10.3	7.2, 6.6	13.4, 8.1
	SD, SE	5512.07, 1299.21	8441.30, 1492.23	7465.15, 1055.73	36.96, 6.75	5.95, 0.99	25.99, 3.20
	MEDIAN	4994.3	3682.4	4002.7	6.2	6.2	6.2
	MIN, MAX	78.9, 23131.1	201.6, 39022.0	78.9, 39022.0	6.2, 151.0	6.2, 41.9	6.2, 151.0
	5%, 95%	78.9, 23131.1	282.4, 23131.4	282.4, 23131.1	6.2, 128.8	6.2, 7.4	6.2, 41.9
	BLQ Values Included	0	0	0	18	34	52
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	7884.4, 5377.8	7559.2, 4292.7	7678.6, 4663.2	31.2, 9.3	7.0, 6.6	18.0, 7.7
	SD, SE	5552.14, 1308.65	8815.87, 1583.38	7714.75, 1102.11	118.03, 21.55	3.53, 0.59	79.81, 9.82
	MEDIAN	6126.2	4504.8	5150.2	6.2	6.2	6.2
	MIN, MAX	75.2, 21513.4	414.3, 40900.5	75.2, 40900.5	6.2, 654.7	6.2, 26.5	6.2, 654.7
	5%, 95%	75.2, 21513.4	514.8, 30589.5	514.8, 21513.4	6.2, 35.1	6.2, 12.9	6.2, 26.5
	BLQ Values Included	0	0	0	22	33	55
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	6630.4, 3678.3	7522.2, 5186.3	7192.6, 4567.8	9.3, 7.5	6.3, 6.3	7.6, 6.8
	SD, SE	5541.54, 1344.02	5951.14, 1105.10	5757.14, 848.84	11.07, 2.02	0.40, 0.07	7.55, 0.93
	MEDIAN	5056.5	6925.1	5618.2	6.2	6.2	6.2
	MIN, MAX	32.1, 18534.5	185.0, 22380.2	32.1, 22380.2	6.2, 64.7	6.2, 8.6	6.2, 64.7
	5%, 95%	32.1, 18534.5	1794.6, 21970.2	807.6, 18534.5	6.2, 24.7	6.2, 6.2	6.2, 10.5
	BLQ Values Included	0	0	0	23	35	58
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	7152.5, 4949.8	7220.5, 4403.2	7196.0, 4592.7	20.4, 10.2	6.8, 6.6	13.0, 8.0
	SD, SE	4523.60, 1066.22	7141.56, 1262.46	6274.31, 887.32	47.74, 8.72	2.58, 0.43	32.67, 4.02
	MEDIAN	5838.7	4348.7	5027.4	6.3	6.2	6.2
	MIN, MAX	62.1, 15103.7	404.2, 34100.9	62.1, 34100.9	6.2, 263.2	6.2, 20.3	6.2, 263.2
	5%, 95%	62.1, 15103.7	427.6, 18569.2	427.6, 18191.3	6.2, 60.8	6.2, 13.0	6.2, 20.3

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Cotinine (ng/mL)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1001.8, 749.5	1044.9, 787.0	1029.4, 773.3	2.3, 1.5	1.2, 1.1	1.7, 1.3
	SD, SE	574.80, 135.48	630.99, 115.08	619.01, 87.54	2.91, 0.53	0.68, 0.11	2.08, 0.26
	MEDIAN	925.7	911.1	919.4	1.0	1.0	1.0
	MIN, MAX	19.0, 2263.4	18.2, 2626.8	18.2, 2626.8	1.0, 14.1	1.0, 4.8	1.0, 14.1
	5%, 95%	19.0, 2263.4	226.0, 2534.2	226.0, 2263.4	1.0, 10.0	1.0, 2.2	1.0, 4.8
	BLQ Values Included	0	0	0	19	31	50
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	1183.3, 887.6	1138.3, 880.3	1154.8, 883.0	2.7, 1.6	1.2, 1.1	1.9, 1.3
	SD, SE	626.79, 147.74	877.59, 157.62	788.02, 112.57	4.14, 0.76	0.39, 0.07	2.89, 0.36
	MEDIAN	1065.2	975.4	975.4	1.0	1.0	1.0
	MIN, MAX	15.5, 2343.3	81.5, 4778.6	15.5, 4778.6	1.0, 20.8	1.0, 2.5	1.0, 20.8
	5%, 95%	15.5, 2343.3	221.4, 2646.6	221.4, 2343.3	1.0, 11.7	1.0, 2.4	1.0, 4.1
	BLQ Values Included	0	0	0	18	30	48
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	1107.1, 728.7	1068.7, 908.3	1082.9, 837.2	2.1, 1.4	1.1, 1.0	1.5, 1.2
	SD, SE	744.03, 180.45	570.14, 105.87	632.01, 93.19	3.49, 0.64	0.45, 0.08	2.40, 0.30
	MEDIAN	844.3	1005.9	998.4	1.0	1.0	1.0
	MIN, MAX	6.1, 2858.1	121.1, 2580.2	6.1, 2858.1	1.0, 19.9	1.0, 3.7	1.0, 19.9
	5%, 95%	6.1, 2858.1	311.8, 2101.4	257.2, 2346.7	1.0, 5.3	1.0, 1.2	1.0, 2.8
	BLQ Values Included	0	0	0	18	33	51
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	1101.6, 829.0	1062.8, 856.8	1076.8, 846.7	2.3, 1.6	1.1, 1.1	1.7, 1.3
	SD, SE	549.70, 129.57	659.30, 116.55	616.60, 87.20	2.96, 0.54	0.41, 0.07	2.09, 0.26
	MEDIAN	1065.0	914.3	970.2	1.1	1.0	1.0
	MIN, MAX	13.5, 1962.5	73.6, 3090.2	13.5, 3090.2	1.0, 13.9	1.0, 2.8	1.0, 13.9
	5%, 95%	13.5, 1962.5	275.9, 2617.9	275.9, 1962.5	1.0, 10.6	1.0, 2.7	1.0, 4.1

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Cotinine (nmol/L)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	5685.4, 4253.4	5930.1, 4466.2	5842.0, 4388.4	12.8, 8.8	6.7, 6.3	9.5, 7.3
	SD, SE	3262.01, 768.86	3694.37, 653.08	3512.90, 496.80	16.33, 3.02	3.84, 0.64	11.80, 1.45
	MEDIAN	5253.1	5170.2	5217.3	5.7	5.7	5.7
	MIN, MAX	107.8, 12844.8	103.3, 14907.1	103.3, 14907.1	5.7, 80.0	5.7, 27.2	5.7, 80.0
	5%, 95%	107.8, 12844.8	1282.6, 14381.6	1282.6, 12844.8	5.7, 56.8	5.7, 12.5	5.7, 27.2
	BLQ Values Included	0	0	0	19	31	50
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	6715.1, 5037.2	6459.7, 4995.6	6553.5, 5010.8	15.3, 9.3	6.6, 6.3	10.6, 7.6
	SD, SE	3557.04, 838.40	4980.33, 894.49	4472.01, 638.86	23.49, 4.29	2.21, 0.37	16.37, 2.02
	MEDIAN	6045.1	5535.4	5535.4	5.7	5.7	5.7
	MIN, MAX	88.0, 13298.2	462.5, 27118.6	88.0, 27118.6	5.7, 118.0	5.7, 14.2	5.7, 118.0
	5%, 95%	88.0, 13298.2	1256.4, 15019.5	1256.4, 13298.2	5.7, 66.4	5.7, 13.6	5.7, 23.3
	BLQ Values Included	0	0	0	18	30	48
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	6282.8, 4135.0	6064.6, 5154.5	6145.2, 4751.3	11.7, 8.0	6.2, 6.0	8.7, 6.8
	SD, SE	4222.34, 1024.07	3235.56, 600.83	3586.67, 528.83	19.79, 3.61	2.55, 0.43	13.63, 1.68
	MEDIAN	4791.4	5708.5	5665.7	5.7	5.7	5.7
	MIN, MAX	34.6, 16219.7	687.2, 14642.6	34.6, 16219.7	5.7, 112.9	5.7, 21.0	5.7, 112.9
	5%, 95%	34.6, 16219.7	1769.5, 11925.4	1459.6, 13317.5	5.7, 30.1	5.7, 6.8	5.7, 15.9
	BLQ Values Included	0	0	0	18	33	51
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	6251.7, 4705.3	6031.5, 4862.6	6110.8, 4805.3	13.3, 9.2	6.5, 6.3	9.6, 7.5
	SD, SE	3119.51, 735.28	3741.56, 661.42	3499.18, 494.86	16.80, 3.07	2.35, 0.39	11.85, 1.46
	MEDIAN	6043.6	5188.9	5505.8	6.4	5.7	5.7
	MIN, MAX	76.8, 11137.0	417.7, 17537.1	76.8, 17537.1	5.7, 78.7	5.7, 15.9	5.7, 78.7
	5%, 95%	76.8, 11137.0	1566.0, 14856.4	1566.0, 11137.0	5.7, 60.2	5.7, 15.5	5.7, 23.5

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total 3-hydroxycotinine (ng/mL)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	5422.5, 3090.8	4520.5, 3158.8	4845.2, 3134.1	8.4, 3.6	2.6, 1.7	5.3, 2.4
	SD, SE	6007.04, 1415.87	3406.88, 602.26	4478.12, 633.30	17.48, 3.19	3.60, 0.60	12.32, 1.32
	MEDIAN	3942.6	3835.6	3846.4	3.2	1.1	1.5
	MIN, MAX	57.0, 26581.8	67.5, 15165.6	57.0, 26581.8	1.0, 96.1	1.0, 18.0	1.0, 96.1
	5%, 95%	57.0, 26581.8	547.1, 12291.4	547.1, 12291.4	1.0, 21.5	1.0, 14.4	1.0, 18.0
	BLQ Values Included	0	0	0	8	16	24
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	5759.2, 3582.1	6105.6, 4281.4	5978.4, 4009.9	13.2, 4.2	3.0, 1.9	7.6, 2.8
	SD, SE	5203.34, 1226.44	4702.90, 844.67	4841.56, 691.65	31.84, 5.81	3.73, 0.62	22.05, 2.71
	MEDIAN	4781.9	4802.7	4802.7	2.7	1.3	2.0
	MIN, MAX	53.8, 23327.3	276.3, 16335.0	53.8, 23327.3	1.0, 169.4	1.0, 17.5	1.0, 169.4
	5%, 95%	53.8, 23327.3	968.5, 16284.7	807.0, 16284.7	1.0, 57.6	1.0, 13.6	1.0, 26.2
	BLQ Values Included	0	0	0	2	14	16
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	4831.2, 2900.2	5180.2, 3871.9	5051.2, 3479.7	6.8, 3.1	2.2, 1.6	4.3, 2.2
	SD, SE	3990.41, 967.82	4458.33, 827.89	4249.51, 626.56	12.95, 2.36	2.38, 0.40	9.12, 1.12
	MEDIAN	4218.2	3922.3	4050.7	2.5	1.0	1.4
	MIN, MAX	49.9, 14967.4	703.4, 23404.7	49.9, 23404.7	1.0, 69.1	1.0, 12.5	1.0, 69.1
	5%, 95%	49.9, 14967.4	898.7, 11352.7	703.4, 12479.5	1.0, 21.9	1.0, 6.9	1.0, 15.6
	BLQ Values Included	0	0	0	7	19	26
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	5401.5, 3535.5	5159.8, 3843.3	5246.8, 3729.5	9.5, 4.2	2.6, 1.9	5.7, 2.7
	SD, SE	4129.77, 973.40	3827.67, 676.64	3898.69, 551.36	16.09, 2.94	2.73, 0.46	11.46, 1.41
	MEDIAN	5004.8	3829.5	4786.8	3.5	1.3	2.0
	MIN, MAX	53.6, 18644.1	349.1, 18285.0	53.6, 18644.1	1.0, 66.3	1.0, 12.3	1.0, 66.3
	5%, 95%	53.6, 18644.1	835.5, 11100.3	745.1, 11100.3	1.0, 61.9	1.0, 11.3	1.0, 18.6

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234' for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total 3-hydroxycotinine (nmol/L)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	28213.3, 16081.4	23520.0, 16435.2	25209.6, 16307.0	43.9, 18.6	13.7, 9.0	27.4, 12.5
	SD, SE	31254.60, 7366.79	17726.00, 3133.55	23299.70, 3295.07	90.93, 16.60	18.72, 3.12	64.09, 7.89
	MEDIAN	20513.4	19956.6	20012.6	16.7	5.5	7.8
	MIN, MAX	296.6, 138305.1	351.2, 78906.6	296.6, 138305.1	5.2, 500.0	5.2, 93.7	5.2, 500.0
	5%, 95%	296.6, 138305.0	2846.6, 63952.2	2846.6, 63952.2	5.2, 111.9	5.2, 74.9	5.2, 93.7
	BLQ Values Included	0	0	0	8	16	24
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	29965.1, 18637.5	31767.7, 22275.9	31105.5, 20863.4	68.6, 21.8	15.6, 10.1	39.7, 14.3
	SD, SE	27073.00, 6381.16	24469.20, 4394.80	25190.70, 3598.67	165.69, 30.25	19.44, 3.24	114.71, 14.12
	MEDIAN	24880.2	24988.4	24988.4	14.1	6.8	10.2
	MIN, MAX	279.9, 121371.9	1437.6, 84991.0	279.9, 121371.9	5.2, 881.4	5.2, 91.1	5.2, 881.4
	5%, 95%	279.9, 121372.0	5039.1, 84729.3	4198.8, 84729.3	5.2, 299.7	5.2, 70.8	5.2, 136.3
	BLQ Values Included	0	0	0	2	14	16
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	25136.6, 15089.8	26952.4, 20145.6	26281.4, 18105.1	35.6, 16.4	11.5, 8.3	22.4, 11.3
	SD, SE	20762.10, 5035.55	23196.70, 4307.52	22110.20, 3259.97	67.36, 12.30	12.36, 2.06	47.47, 5.84
	MEDIAN	21947.3	20407.7	21075.5	12.8	5.2	7.3
	MIN, MAX	259.6, 77875.4	3659.8, 121774.7	259.6, 121774.7	5.2, 359.5	5.2, 65.0	5.2, 359.5
	5%, 95%	259.6, 77875.4	4675.9, 59068.1	3659.8, 64930.8	5.2, 113.9	5.2, 35.9	5.2, 81.2
	BLQ Values Included	0	0	0	7	19	26
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	28104.0, 18394.8	26846.2, 19996.4	27299.0, 19404.3	49.4, 22.0	13.6, 9.7	29.8, 14.1
	SD, SE	21487.20, 5064.58	19915.40, 3520.57	20284.90, 2868.72	83.69, 15.28	14.23, 2.37	59.64, 7.34
	MEDIAN	26040.0	19924.9	24905.7	18.2	6.5	10.2
	MIN, MAX	278.7, 97005.2	1816.2, 95136.9	278.7, 97005.2	5.2, 344.8	5.2, 64.0	5.2, 344.8
	5%, 95%	278.7, 97005.2	4347.1, 57754.9	3876.6, 57754.9	5.4, 322.2	5.2, 58.8	5.2, 96.8

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free 3-hydroxycotinine (ng/mL)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	3751.4, 2167.4	3436.3, 2397.8	3549.7, 2312.1	6.9, 3.2	2.3, 1.6	4.4, 2.2
	SD, SE	3939.23, 928.49	2714.78, 479.91	3173.27, 448.77	13.99, 2.55	3.15, 0.53	9.90, 1.22
	MEDIAN	3027.7	3110.5	3110.5	3.0	1.1	1.4
	MIN, MAX	30.1, 17333.8	52.2, 12964.7	30.1, 17333.8	1.0, 77.2	1.0, 17.7	1.0, 77.2
	5%, 95%	30.1, 17333.8	422.2, 9882.6	422.2, 9882.6	1.0, 16.5	1.0, 10.2	1.0, 16.4
	BLQ Values Included	0	0	0	7	16	23
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	4429.1, 2668.3	4838.9, 3296.8	4688.4, 3050.3	10.6, 3.6	2.4, 1.7	6.1, 2.4
	SD, SE	4222.63, 995.28	3905.64, 701.47	3986.05, 569.44	25.38, 4.63	2.82, 0.47	17.57, 2.16
	MEDIAN	3357.9	3464.4	3435.7	2.5	1.2	1.7
	MIN, MAX	26.9, 18865.3	219.4, 13348.8	26.9, 18865.3	1.0, 135.0	1.0, 15.9	1.0, 135.0
	5%, 95%	26.9, 18865.3	731.1, 13308.1	692.4, 13308.1	1.0, 45.6	1.0, 7.0	1.0, 21.4
	BLQ Values Included	0	0	0	3	15	18
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	3384.2, 2057.2	3785.0, 2883.8	3636.9, 2545.4	5.5, 2.7	1.9, 1.5	3.5, 1.9
	SD, SE	2434.95, 590.56	3055.44, 567.38	2820.50, 415.86	10.33, 1.89	1.85, 0.31	7.27, 0.89
	MEDIAN	3560.9	3001.5	3045.4	2.2	1.0	1.3
	MIN, MAX	20.4, 9253.1	525.1, 15599.2	20.4, 15599.2	1.0, 56.0	1.0, 9.7	1.0, 56.0
	5%, 95%	20.4, 9253.1	627.6, 8394.0	525.1, 8394.0	1.0, 17.1	1.0, 5.8	1.0, 10.9
	BLQ Values Included	0	0	0	8	23	31
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	3908.9, 2541.6	3939.4, 2916.7	3928.4, 2775.7	7.7, 3.6	2.2, 1.7	4.7, 2.4
	SD, SE	2969.07, 699.82	2932.97, 522.02	2928.37, 414.13	13.00, 2.37	2.02, 0.34	9.23, 1.14
	MEDIAN	3787.3	3063.3	3463.0	2.9	1.4	1.8
	MIN, MAX	25.8, 13647.0	265.6, 13970.9	25.8, 13970.9	1.0, 52.6	1.0, 9.0	1.0, 52.6
	5%, 95%	25.8, 13647.0	601.4, 8965.5	601.4, 8965.5	1.0, 51.5	1.0, 8.8	1.0, 14.3

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free 3-hydroxycotinine (nmol/L)

Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	19518.5, 11277.0	17879.0, 12475.5	18469.2, 12030.0	36.0, 16.5	11.8, 8.2	22.8, 11.3
	SD, SE	20495.80, 4830.91	14125.00, 2496.97	16510.50, 2334.94	72.77, 13.29	16.40, 2.73	51.53, 6.34
	MEDIAN	15752.9	16183.9	16183.9	15.4	5.7	7.1
	MIN, MAX	156.6, 90187.8	271.6, 67455.3	156.6, 90187.8	5.2, 401.7	5.2, 92.1	5.2, 401.7
	5%, 95%	156.6, 90187.8	2196.7, 51419.2	2196.7, 51419.2	5.2, 85.8	5.2, 53.1	5.2, 85.3
Week 2	BLQ Values Included	0	0	0	7	16	23
	N	18	31	49	30	36	66
	MEAN, GEO MEAN	23044.8, 13883.4	25177.0, 17153.0	24393.8, 15870.9	55.3, 18.5	12.4, 8.9	31.9, 12.4
	SD, SE	21970.40, 5178.46	20321.10, 3649.77	20739.40, 2962.78	132.05, 24.11	14.69, 2.45	91.42, 11.25
	MEDIAN	17470.9	18025.3	17875.9	12.8	6.2	8.8
	MIN, MAX	140.0, 98156.2	1141.5, 69453.8	140.0, 98156.2	5.2, 702.4	5.2, 82.7	5.2, 702.4
Week 3	5%, 95%	140.0, 98156.2	3803.9, 69242.0	3602.6, 69242.0	5.2, 237.3	5.2, 36.4	5.2, 111.3
	BLQ Values Included	0	0	0	3	15	18
	N	17	29	46	30	36	66
	MEAN, GEO MEAN	17608.0, 10703.4	19693.4, 15004.2	18922.7, 13243.4	28.6, 14.3	9.8, 7.6	18.3, 10.1
	SD, SE	12669.00, 3072.69	15897.50, 2952.08	14675.10, 2163.72	53.77, 9.82	9.65, 1.61	37.80, 4.65
	MEDIAN	18527.4	15616.8	15845.0	11.2	5.2	6.8
Overall*	MIN, MAX	106.1, 48143.9	2732.1, 81162.6	106.1, 81162.6	5.2, 291.4	5.2, 50.5	5.2, 291.4
	5%, 95%	106.1, 48143.9	3265.4, 43674.0	2732.1, 43674.0	5.2, 89.0	5.2, 30.2	5.2, 56.7
	BLQ Values Included	0	0	0	8	23	31
	N	18	32	50	30	36	66
	MEAN, GEO MEAN	20338.0, 13223.8	20496.4, 15175.5	20439.3, 14441.8	40.0, 18.8	11.3, 8.8	24.4, 12.4
	SD, SE	15448.10, 3641.14	15364.30, 2716.05	15236.30, 2154.74	67.63, 12.35	10.50, 1.75	48.03, 5.91
Overall*	MEDIAN	19705.4	15938.4	18017.8	14.9	6.9	9.3
	MIN, MAX	134.2, 71005.4	1381.7, 72690.6	134.2, 72690.6	5.2, 273.7	5.2, 46.7	5.2, 273.7
	5%, 95%	134.2, 71005.4	3129.3, 46647.3	3129.3, 46647.3	5.2, 268.1	5.2, 45.6	5.2, 74.6

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Nicotine (nmol/L)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	1	2	3
	MEAN, GEO MEAN	15881.3, 12002.3	3716.4, 3522.0	9798.9, 6501.7	12.7, 12.7	12.7, 12.7	12.7, 12.7
	SD, SE	12560.30, 7251.68	1519.43, 877.25	10412.60, 4250.94	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	14410.2	3272.1	4765.0	12.7	12.7	12.7
	MIN, MAX	4121.4, 29112.4	2468.7, 5408.5	2468.7, 29112.4	12.7, 12.7	12.7, 12.7	12.7, 12.7
	5%, 95%	4121.4, 29112.4	2468.7, 5408.5	2468.7, 29112.4	NA, NA	12.7, 12.7	12.7, 12.7
	BLQ Values Included	0	0	0	1	2	3
Week 2	N	3	3	6	2	3	5
	MEAN, GEO MEAN	13046.6, 10206.2	4821.8, 4348.3	8934.2, 6661.8	12.7, 12.7	24.9, 20.0	20.0, 16.7
	SD, SE	9005.77, 5199.48	2813.16, 1624.18	7476.72, 3052.36	0.00, 0.00	21.19, 12.23	16.41, 7.34
	MEDIAN	14296.8	3453.4	5769.3	12.7	12.7	12.7
	MIN, MAX	3481.1, 21362.0	2954.7, 8057.4	2954.7, 21362.0	12.7, 12.7	12.7, 49.4	12.7, 49.4
	5%, 95%	3481.1, 21362.0	2954.7, 8057.4	2954.7, 21362.0	12.7, 12.7	12.7, 49.4	12.7, 49.4
	BLQ Values Included	0	0	0	2	2	4
Week 3	N	2	3	5	4	3	7
	MEAN, GEO MEAN	5553.6, 4245.8	5049.5, 4741.8	5231.1, 4536.8	12.7, 12.7	12.7, 12.7	12.7, 12.7
	SD, SE	5062.67, 3579.85	1969.90, 1137.32	2902.43, 1298.01	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	5553.6	5824.0	5824.0	12.7	12.7	12.7
	MIN, MAX	1973.7, 9133.4	2810.1, 6514.5	1973.7, 9133.4	12.7, 12.7	12.7, 12.7	12.7, 12.7
	5%, 95%	1973.7, 9133.4	2810.1, 6514.5	1973.7, 9133.4	12.7, 12.7	12.7, 12.7	12.7, 12.7
	BLQ Values Included	0	0	0	4	3	7
Overall*	N	3	3	6	4	3	7
	MEAN, GEO MEAN	12471.6, 9691.8	4529.3, 4244.4	8500.5, 6413.7	12.7, 12.7	16.8, 15.9	14.4, 14.0
	SD, SE	8496.37, 4905.38	1980.61, 1143.50	7026.29, 2868.47	0.00, 0.00	7.04, 4.07	4.61, 1.74
	MEDIAN	14353.5	4183.2	5421.7	12.7	12.7	12.7
	MIN, MAX	3192.1, 19869.3	2744.5, 6660.1	2744.5, 19869.3	12.7, 12.7	12.7, 24.9	12.7, 24.9
	5%, 95%	3192.1, 19869.3	2744.5, 6660.1	2744.5, 19869.3	12.7, 12.7	12.7, 24.9	12.7, 24.9

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Nicotine (ng/mL)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	1	2	3
	MEAN, GEO MEAN	2575.9, 1946.8	602.8, 571.3	1589.4, 1054.6	2.1, 2.1	2.1, 2.1	2.1, 2.1
	SD, SE	2037.26, 1176.21	246.49, 142.31	1688.92, 689.50	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	2337.3	530.7	772.9	2.1	2.1	2.1
	MIN, MAX	668.5, 4722.0	400.4, 877.3	400.4, 4722.0	2.1, 2.1	2.1, 2.1	2.1, 2.1
	5%, 95%	668.5, 4722.0	400.4, 877.3	400.4, 4722.0	NA, NA	2.1, 2.1	2.1, 2.1
	BLQ Values Included	0	0	0	1	2	3
Week 2	N	3	3	6	2	3	5
	MEAN, GEO MEAN	2116.1, 1655.4	782.1, 705.3	1449.1, 1080.5	2.1, 2.1	4.1, 3.3	3.3, 2.7
	SD, SE	1460.74, 843.36	456.28, 263.43	1212.72, 495.09	0.00, 0.00	3.41, 1.97	2.64, 1.18
	MEDIAN	2318.9	560.1	935.8	2.1	2.1	2.1
	MIN, MAX	564.6, 3464.9	479.3, 1306.9	479.3, 3464.9	2.1, 2.1	2.1, 8.0	2.1, 8.0
	5%, 95%	564.6, 3464.9	479.3, 1306.9	479.3, 3464.9	2.1, 2.1	2.1, 8.0	2.1, 8.0
	BLQ Values Included	0	0	0	2	2	4
Week 3	N	2	3	5	4	3	7
	MEAN, GEO MEAN	900.8, 688.6	819.1, 769.1	851.7, 735.9	2.1, 2.1	2.1, 2.1	2.1, 2.1
	SD, SE	821.16, 580.65	319.54, 184.49	470.78, 210.54	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	900.8	944.7	944.7	2.1	2.1	2.1
	MIN, MAX	320.1, 1481.4	455.8, 1056.7	320.1, 1481.4	2.1, 2.1	2.1, 2.1	2.1, 2.1
	5%, 95%	320.1, 1481.4	455.8, 1056.7	320.1, 1481.4	2.1, 2.1	2.1, 2.1	2.1, 2.1
	BLQ Values Included	0	0	0	4	3	7
Overall*	N	3	3	6	4	3	7
	MEAN, GEO MEAN	2022.9, 1571.9	734.7, 688.5	1378.8, 1040.3	2.1, 2.1	2.8, 2.6	2.4, 2.3
	SD, SE	1378.14, 795.67	321.25, 185.48	1139.66, 465.26	0.00, 0.00	1.15, 0.67	0.76, 0.29
	MEDIAN	2328.1	678.5	879.4	2.1	2.1	2.1
	MIN, MAX	517.7, 3222.8	445.2, 1080.3	445.2, 3222.8	2.1, 2.1	2.1, 4.1	2.1, 4.1
	5%, 95%	517.7, 3222.8	445.2, 1080.3	445.2, 3222.8	2.1, 2.1	2.1, 4.1	2.1, 4.1
	BLQ Values Included	0	0	0	4	3	7

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Nicotine (nmol/L)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	2	1	3
	MEAN, GEO MEAN	12271.5, 9840.3	2122.6, 2006.9	7197.1, 4444.0	3.4, 3.4	3.4, 3.4	3.4, 3.4
	SD, SE	8510.73, 4913.67	871.69, 503.27	7757.37, 3166.93	0.00, 0.00	NA, NA	0.00, 0.00
	MEDIAN	12357.7	1940.2	3394.6	3.4	3.4	3.4
	MIN, MAX	3718.0, 20738.8	1356.6, 3071.1	1356.6, 20738.8	3.4, 3.4	3.4, 3.4	3.4, 3.4
	5%, 95%	3718.0, 20738.8	1356.6, 3071.1	1356.6, 20738.8	3.4, 3.4	NA, NA	3.4, 3.4
	BLQ Values Included	0	0	0	2	1	3
Week 2	N	3	3	6		2	2
	MEAN, GEO MEAN	9033.2, 6684.7	3079.6, 2638.5	6056.4, 4199.7		3.4, 3.4	3.4, 3.4
	SD, SE	6416.07, 3704.32	2203.98, 1272.47	5389.15, 2200.11		0.00, 0.00	0.00, 0.00
	MEDIAN	10778.2	1809.1	3774.8		3.4	3.4
	MIN, MAX	1925.1, 14396.2	1805.1, 5624.5	1805.1, 14396.2		3.4, 3.4	3.4, 3.4
	5%, 95%	1925.1, 14396.2	1805.1, 5624.5	1805.1, 14396.2		3.4, 3.4	3.4, 3.4
	BLQ Values Included	0	0	0		2	2
Week 3	N	2	3	5	2	2	4
	MEAN, GEO MEAN	3417.6, 2856.3	3389.0, 3052.9	3400.4, 2972.7	3.4, 3.4	3.4, 3.4	3.4, 3.4
	SD, SE	2653.91, 1876.60	1624.09, 937.67	1754.96, 784.84	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	3417.6	4113.9	4113.9	3.4	3.4	3.4
	MIN, MAX	1541.0, 5294.2	1528.7, 4524.4	1528.7, 5294.2	3.4, 3.4	3.4, 3.4	3.4, 3.4
	5%, 95%	1541.0, 5294.2	1528.7, 4524.4	1528.7, 5294.2	3.4, 3.4	3.4, 3.4	3.4, 3.4
	BLQ Values Included	0	0	0	2	2	4
Overall*	N	3	3	6	3	3	6
	MEAN, GEO MEAN	9146.4, 7200.5	2863.7, 2640.9	6005.1, 4360.7	3.4, 3.4	3.4, 3.4	3.4, 3.4
	SD, SE	5924.46, 3420.49	1355.68, 782.70	5159.10, 2106.19	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	11568.0	2756.6	3513.2	3.4	3.4	3.4
	MIN, MAX	2394.7, 13476.4	1564.8, 4269.8	1564.8, 13476.4	3.4, 3.4	3.4, 3.4	3.4, 3.4
	5%, 95%	2394.7, 13476.4	1564.8, 4269.8	1564.8, 13476.4	3.4, 3.4	3.4, 3.4	3.4, 3.4

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Nicotine (ng/mL)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	2	1	3
	MEAN, GEO MEAN	1990.4, 1596.1	344.3, 325.5	1167.4, 720.8	0.6, 0.6	0.6, 0.6	0.6, 0.6
	SD, SE	1380.40, 796.98	141.39, 81.63	1258.24, 513.67	0.00, 0.00	NA, NA	0.00, 0.00
	MEDIAN	2004.4	314.7	550.6	0.6	0.6	0.6
	MIN, MAX	603.1, 3363.8	220.0, 498.1	220.0, 3363.8	0.6, 0.6	0.6, 0.6	0.6, 0.6
	5%, 95%	603.1, 3363.8	220.0, 498.1	220.0, 3363.8	0.6, 0.6	NA, NA	0.6, 0.6
	BLQ Values Included	0	0	0	2	1	3
Week 2	N	3	3	6		2	2
	MEAN, GEO MEAN	1465.2, 1084.3	499.5, 427.9	982.4, 681.2		0.6, 0.6	0.6, 0.6
	SD, SE	1040.67, 600.83	357.50, 206.40	874.12, 356.86		0.00, 0.00	0.00, 0.00
	MEDIAN	1748.2	293.4	612.3		0.6	0.6
	MIN, MAX	312.3, 2335.1	292.8, 912.3	292.8, 2335.1		0.6, 0.6	0.6, 0.6
	5%, 95%	312.3, 2335.1	292.8, 912.3	292.8, 2335.1		0.6, 0.6	0.6, 0.6
	BLQ Values Included	0	0	0		2	2
Week 3	N	2	3	5	2	2	4
	MEAN, GEO MEAN	554.4, 463.3	549.7, 495.2	551.6, 482.2	0.6, 0.6	0.6, 0.6	0.6, 0.6
	SD, SE	430.42, 304.35	263.42, 152.09	284.63, 127.29	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	554.4	667.3	667.3	0.6	0.6	0.6
	MIN, MAX	250.0, 858.7	248.0, 733.9	248.0, 858.7	0.6, 0.6	0.6, 0.6	0.6, 0.6
	5%, 95%	250.0, 858.7	248.0, 733.9	248.0, 858.7	0.6, 0.6	0.6, 0.6	0.6, 0.6
	BLQ Values Included	0	0	0	2	2	4
Overall*	N	3	3	6	3	3	6
	MEAN, GEO MEAN	1483.6, 1168.0	464.5, 428.3	974.0, 707.3	0.6, 0.6	0.6, 0.6	0.6, 0.6
	SD, SE	960.91, 554.78	219.92, 126.97	836.80, 341.62	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	1876.3	447.1	569.9	0.6	0.6	0.6
	MIN, MAX	388.5, 2185.9	253.8, 692.6	253.8, 2185.9	0.6, 0.6	0.6, 0.6	0.6, 0.6
	5%, 95%	388.5, 2185.9	253.8, 692.6	253.8, 2185.9	0.6, 0.6	0.6, 0.6	0.6, 0.6

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Cotinine (nmol/L)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	2	6
	MEAN, GEO MEAN	18992.3, 11773.2	9720.5, 9427.6	14356.4, 10535.4	11.0, 11.0	11.0, 11.0	11.0, 11.0
	SD, SE	18911.30, 10918.40	2975.82, 1718.09	13129.60, 5360.14	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	14304.5	9064.9	11017.2	11.0	11.0	11.0
	MIN, MAX	2865.9, 39806.6	7127.2, 12969.5	2865.9, 39806.6	11.0, 11.0	11.0, 11.0	11.0, 11.0
	5%, 95%	2865.9, 39806.6	7127.2, 12969.5	2865.9, 39806.6	11.0, 11.0	11.0, 11.0	11.0, 11.0
	BLQ Values Included	0	0	0	4	2	6
Week 2	N	3	3	6	4	3	7
	MEAN, GEO MEAN	19069.8, 13837.6	10237.0, 10000.7	14653.4, 11763.7	11.0, 11.0	11.0, 11.0	11.0, 11.0
	SD, SE	13857.20, 8000.46	2815.53, 1625.55	10167.90, 4151.01	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	22533.0	8701.3	11093.9	11.0	11.0	11.0
	MIN, MAX	3809.5, 30867.0	8523.3, 13486.5	3809.5, 30867.0	11.0, 11.0	11.0, 11.0	11.0, 11.0
	5%, 95%	3809.5, 30867.0	8523.3, 13486.5	3809.5, 30867.0	11.0, 11.0	11.0, 11.0	11.0, 11.0
	BLQ Values Included	0	0	0	4	3	7
Week 3	N	2	3	5	4	3	7
	MEAN, GEO MEAN	11020.5, 5984.5	9272.5, 9086.7	9971.7, 7688.8	11.0, 11.0	11.0, 11.0	11.0, 11.0
	SD, SE	13087.10, 9253.95	2353.34, 1358.70	6819.34, 3049.70	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	11020.5	8330.8	8330.8	11.0	11.0	11.0
	MIN, MAX	1766.5, 20274.4	7535.9, 11950.9	1766.5, 20274.4	11.0, 11.0	11.0, 11.0	11.0, 11.0
	5%, 95%	1766.5, 20274.4	7535.9, 11950.9	1766.5, 20274.4	11.0, 11.0	11.0, 11.0	11.0, 11.0
	BLQ Values Included	0	0	0	4	3	7
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	17182.9, 11625.7	9743.4, 9522.3	13463.2, 10521.5	11.0, 11.0	11.0, 11.0	11.0, 11.0
	SD, SE	13792.60, 7963.16	2653.99, 1532.28	9773.22, 3989.90	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	18418.8	8374.7	10588.5	11.0	11.0	11.0
	MIN, MAX	2814.0, 30316.0	8053.1, 12802.3	2814.0, 30316.0	11.0, 11.0	11.0, 11.0	11.0, 11.0
	5%, 95%	2814.0, 30316.0	8053.1, 12802.3	2814.0, 30316.0	11.0, 11.0	11.0, 11.0	11.0, 11.0

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4.2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total Cotinine (ng/mL)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	2	6
	MEAN, GEO MEAN	3346.5, 2074.5	1712.7, 1661.1	2529.6, 1856.3	1.9, 1.9	1.9, 1.9	1.9, 1.9
	SD, SE	3332.13, 1923.81	524.33, 302.72	2313.43, 944.45	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	2520.5	1597.2	1941.2	1.9	1.9	1.9
	MIN, MAX	505.0, 7013.9	1255.8, 2285.2	505.0, 7013.9	1.9, 1.9	1.9, 1.9	1.9, 1.9
	5%, 95%	505.0, 7013.9	1255.8, 2285.2	505.0, 7013.9	1.9, 1.9	1.9, 1.9	1.9, 1.9
	BLQ Values Included	0	0	0	4	2	6
Week 2	N	3	3	6	4	3	7
	MEAN, GEO MEAN	3360.1, 2438.1	1803.8, 1762.1	2581.9, 2072.8	1.9, 1.9	1.9, 1.9	1.9, 1.9
	SD, SE	2441.67, 1409.70	496.08, 286.41	1791.59, 731.41	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	3970.3	1533.2	1954.8	1.9	1.9	1.9
	MIN, MAX	671.2, 5438.8	1501.8, 2376.3	671.2, 5438.8	1.9, 1.9	1.9, 1.9	1.9, 1.9
	5%, 95%	671.2, 5438.8	1501.8, 2376.3	671.2, 5438.8	1.9, 1.9	1.9, 1.9	1.9, 1.9
	BLQ Values Included	0	0	0	4	3	7
Week 3	N	2	3	5	4	3	7
	MEAN, GEO MEAN	1941.8, 1054.5	1633.8, 1601.1	1757.0, 1354.8	1.9, 1.9	1.9, 1.9	1.9, 1.9
	SD, SE	2305.88, 1630.50	414.64, 239.39	1201.54, 537.34	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	1941.8	1467.9	1467.9	1.9	1.9	1.9
	MIN, MAX	311.3, 3572.3	1327.8, 2105.7	311.3, 3572.3	1.9, 1.9	1.9, 1.9	1.9, 1.9
	5%, 95%	311.3, 3572.3	1327.8, 2105.7	311.3, 3572.3	1.9, 1.9	1.9, 1.9	1.9, 1.9
	BLQ Values Included	0	0	0	4	3	7
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	3027.6, 2048.4	1716.8, 1677.8	2372.2, 1853.9	1.9, 1.9	1.9, 1.9	1.9, 1.9
	SD, SE	2430.28, 1403.12	467.59, 269.96	1722.05, 703.03	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	3245.4	1475.6	1865.7	1.9	1.9	1.9
	MIN, MAX	495.8, 5341.7	1419.0, 2255.7	495.8, 5341.7	1.9, 1.9	1.9, 1.9	1.9, 1.9
	5%, 95%	495.8, 5341.7	1419.0, 2255.7	495.8, 5341.7	1.9, 1.9	1.9, 1.9	1.9, 1.9

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Cotinine (nmol/L)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	3	7
	MEAN, GEO MEAN	6583.8, 5308.2	3693.7, 3619.1	5138.7, 4383.0	7.6, 5.0	3.1, 3.1	5.6, 4.1
	SD, SE	4959.84, 2863.57	939.49, 542.41	3563.54, 1454.81	8.90, 4.45	0.00, 0.00	6.73, 2.54
	MEDIAN	5463.6	3338.5	4048.8	3.1	3.1	3.1
	MIN, MAX	2279.8, 12007.9	2983.6, 4759.0	2279.8, 12007.9	3.1, 20.9	3.1, 3.1	3.1, 20.9
	5%, 95%	2279.8, 12007.9	2983.6, 4759.0	2279.8, 12007.9	3.1, 20.9	3.1, 3.1	3.1, 20.9
	BLQ Values Included	0	0	0	3	3	6
Week 2	N	3	3	6	4	4	8
	MEAN, GEO MEAN	6439.9, 5581.3	4243.9, 4212.0	5341.9, 4848.5	3.1, 3.1	3.1, 3.1	3.1, 3.1
	SD, SE	3631.27, 2096.51	620.20, 358.07	2622.04, 1070.44	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	7090.1	4495.7	4597.2	3.1	3.1	3.1
	MIN, MAX	2527.5, 9702.2	3537.4, 4698.6	2527.5, 9702.2	3.1, 3.1	3.1, 3.1	3.1, 3.1
	5%, 95%	2527.5, 9702.2	3537.4, 4698.6	2527.5, 9702.2	3.1, 3.1	3.1, 3.1	3.1, 3.1
	BLQ Values Included	0	0	0	4	4	8
Week 3	N	2	3	5	3	4	7
	MEAN, GEO MEAN	4650.6, 3439.8	3602.1, 3500.7	4021.5, 3476.2	3.1, 3.1	3.1, 3.1	3.1, 3.1
	SD, SE	4426.13, 3129.75	1094.83, 632.10	2413.87, 1079.52	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	4650.6	3087.7	3087.7	3.1	3.1	3.1
	MIN, MAX	1520.8, 7780.3	2859.2, 4859.4	1520.8, 7780.3	3.1, 3.1	3.1, 3.1	3.1, 3.1
	5%, 95%	1520.8, 7780.3	2859.2, 4859.4	1520.8, 7780.3	3.1, 3.1	3.1, 3.1	3.1, 3.1
	BLQ Values Included	0	0	0	3	4	7
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	6072.1, 5067.8	3846.5, 3787.3	4959.3, 4381.0	4.6, 4.0	3.1, 3.1	3.8, 3.5
	SD, SE	3864.42, 2231.12	841.91, 486.07	2782.63, 1136.00	2.95, 1.48	0.00, 0.00	2.09, 0.74
	MEDIAN	6276.9	3640.6	4206.5	3.1	3.1	3.1
	MIN, MAX	2109.4, 9830.1	3126.7, 4772.3	2109.4, 9830.1	3.1, 9.0	3.1, 3.1	3.1, 9.0
	5%, 95%	2109.4, 9830.1	3126.7, 4772.3	2109.4, 9830.1	3.1, 9.0	3.1, 3.1	3.1, 9.0

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free Cotinine (ng/mL)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	3	7
	MEAN, GEO MEAN	1160.1, 935.3	650.8, 637.7	905.4, 772.3	1.3, 0.8	0.5, 0.5	1.0, 0.7
	SD, SE	873.93, 504.56	165.53, 95.57	627.91, 256.34	1.60, 0.80	0.00, 0.00	1.21, 0.46
	MEDIAN	962.7	588.2	713.4	0.5	0.5	0.5
	MIN, MAX	401.7, 2115.8	525.7, 838.5	401.7, 2115.8	0.5, 3.7	0.5, 0.5	0.5, 3.7
	5%, 95%	401.7, 2115.8	525.7, 838.5	401.7, 2115.8	0.5, 3.7	0.5, 0.5	0.5, 3.7
Week 2	BLQ Values Included	0	0	0	3	3	6
	N	3	3	6	4	4	8
	MEAN, GEO MEAN	1134.7, 983.4	747.8, 742.1	941.2, 854.3	0.5, 0.5	0.5, 0.5	0.5, 0.5
	SD, SE	639.84, 369.41	109.27, 63.09	462.01, 188.61	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	1249.3	792.1	810.0	0.5	0.5	0.5
	MIN, MAX	445.3, 1709.5	623.3, 827.9	445.3, 1709.5	0.5, 0.5	0.5, 0.5	0.5, 0.5
Week 3	5%, 95%	445.3, 1709.5	623.3, 827.9	445.3, 1709.5	0.5, 0.5	0.5, 0.5	0.5, 0.5
	BLQ Values Included	0	0	0	4	4	8
	N	2	3	5	3	4	7
	MEAN, GEO MEAN	819.5, 606.1	634.7, 616.8	708.6, 612.5	0.5, 0.5	0.5, 0.5	0.5, 0.5
	SD, SE	779.87, 551.45	192.88, 111.36	425.31, 190.20	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	819.5	544.1	544.1	0.5	0.5	0.5
Overall*	MIN, MAX	268.0, 1370.9	503.8, 856.2	268.0, 1370.9	0.5, 0.5	0.5, 0.5	0.5, 0.5
	5%, 95%	268.0, 1370.9	503.8, 856.2	268.0, 1370.9	0.5, 0.5	0.5, 0.5	0.5, 0.5
	BLQ Values Included	0	0	0	3	4	7
	N	3	3	6	4	4	8
	MEAN, GEO MEAN	1069.9, 893.0	677.8, 667.3	873.9, 771.9	0.8, 0.7	0.5, 0.5	0.6, 0.6
	SD, SE	680.92, 393.13	148.36, 85.66	490.31, 200.17	0.55, 0.28	0.00, 0.00	0.39, 0.14
Overall*	MEDIAN	1106.0	641.5	741.2	0.5	0.5	0.5
	MIN, MAX	371.7, 1732.1	550.9, 840.9	371.7, 1732.1	0.5, 1.6	0.5, 0.5	0.5, 1.6
	5%, 95%	371.7, 1732.1	550.9, 840.9	371.7, 1732.1	0.5, 1.6	0.5, 0.5	0.5, 1.6

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., <1.234* will be used as 1.234*) for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total 3-hydroxycotinine (nmol/L)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	2	3	5
	MEAN, GEO MEAN	19663.7, 17523.9	17857.8, 17465.3	18760.8, 17494.6	28.5, 23.5	21.9, 18.5	24.5, 20.3
	SD, SE	9744.29, 5625.87	4337.31, 2504.15	6817.90, 2783.39	22.70, 16.05	16.45, 9.50	16.64, 7.44
	MEDIAN	24995.6	20281.3	20361.6	28.5	12.4	12.4
	MIN, MAX	8417.0, 25578.5	12850.4, 20441.8	8417.0, 25578.5	12.4, 44.5	12.4, 40.9	12.4, 44.5
	5%, 95%	8417.0, 25578.5	12850.4, 20441.8	8417.0, 25578.5	12.4, 44.5	12.4, 40.9	12.4, 44.5
	BLQ Values Included	0	0	0	1	2	3
Week 2	N	3	3	6	3	2	5
	MEAN, GEO MEAN	22250.3, 18298.4	17703.7, 16917.1	19977.0, 17594.2	22.2, 18.6	12.4, 12.4	18.3, 15.8
	SD, SE	15078.20, 8705.42	6696.93, 3866.47	10727.60, 4379.54	17.03, 9.83	0.00, 0.00	13.19, 5.90
	MEDIAN	21500.8	15546.0	18523.4	12.4	12.4	12.4
	MIN, MAX	7560.8, 37689.3	12351.6, 25213.5	7560.8, 37689.3	12.4, 41.9	12.4, 12.4	12.4, 41.9
	5%, 95%	7560.8, 37689.3	12351.6, 25213.5	7560.8, 37689.3	12.4, 41.9	12.4, 12.4	12.4, 41.9
	BLQ Values Included	0	0	0	2	2	4
Week 3	N	2	3	5	3	2	5
	MEAN, GEO MEAN	9886.9, 8143.2	14951.2, 12532.8	12925.5, 10547.5	12.4, 12.4	12.4, 12.4	12.4, 12.4
	SD, SE	7929.50, 5607.00	11304.30, 6526.57	9343.85, 4178.70	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	9886.9	9437.8	9437.8	12.4	12.4	12.4
	MIN, MAX	4279.9, 15493.9	7461.5, 27954.4	4279.9, 27954.4	12.4, 12.4	12.4, 12.4	12.4, 12.4
	5%, 95%	4279.9, 15493.9	7461.5, 27954.4	4279.9, 27954.4	12.4, 12.4	12.4, 12.4	12.4, 12.4
	BLQ Values Included	0	0	0	3	2	5
Overall*	N	3	3	6	3	3	6
	MEAN, GEO MEAN	19683.3, 16403.7	16837.6, 16021.8	18260.5, 16211.6	19.2, 17.2	21.9, 18.5	20.6, 17.8
	SD, SE	12469.60, 7199.31	6747.46, 3895.65	9101.47, 3715.66	11.84, 6.83	16.45, 9.50	12.90, 5.27
	MEDIAN	20663.4	14023.6	17343.5	12.4	12.4	12.4
	MIN, MAX	6752.6, 31633.9	11952.6, 24536.6	6752.6, 31633.9	12.4, 32.9	12.4, 40.9	12.4, 40.9
	5%, 95%	6752.6, 31633.9	11952.6, 24536.6	6752.6, 31633.9	12.4, 32.9	12.4, 40.9	12.4, 40.9

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., <1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Total 3-hydroxycotinine (ng/mL)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	2	3	5
	MEAN, GEO MEAN	3779.4, 3368.1	3432.3, 3356.8	3605.8, 3362.4	5.5, 4.5	4.2, 3.6	4.7, 3.9
	SD, SE	1872.90, 1081.32	833.66, 481.32	1310.43, 534.98	4.38, 3.10	3.18, 1.83	3.21, 1.44
	MEDIAN	4804.2	3898.1	3913.5	5.5	2.4	2.4
	MIN, MAX	1617.7, 4916.2	2469.8, 3928.9	1617.7, 4916.2	2.4, 8.6	2.4, 7.9	2.4, 8.6
	5%, 95%	1617.7, 4916.2	2469.8, 3928.9	1617.7, 4916.2	2.4, 8.6	2.4, 7.9	2.4, 8.6
Week 2	BLQ Values Included	0	0	0	1	2	3
	N	3	3	6	3	2	5
	MEAN, GEO MEAN	4276.5, 3517.0	3402.6, 3251.4	3839.6, 3381.6	4.3, 3.6	2.4, 2.4	3.5, 3.1
	SD, SE	2898.04, 1673.18	1287.13, 743.12	2061.85, 841.75	3.29, 1.90	0.00, 0.00	2.55, 1.14
	MEDIAN	4132.5	2987.9	3560.2	2.4	2.4	2.4
	MIN, MAX	1453.2, 7243.9	2374.0, 4846.0	1453.2, 7243.9	2.4, 8.1	2.4, 2.4	2.4, 8.1
Week 3	5%, 95%	1453.2, 7243.9	2374.0, 4846.0	1453.2, 7243.9	2.4, 8.1	2.4, 2.4	2.4, 8.1
	BLQ Values Included	0	0	0	2	2	4
	N	2	3	5	3	2	5
	MEAN, GEO MEAN	1900.3, 1565.1	2873.6, 2408.8	2484.3, 2027.2	2.4, 2.4	2.4, 2.4	2.4, 2.4
	SD, SE	1524.03, 1077.65	2172.69, 1254.40	1795.88, 803.14	0.00, 0.00	0.00, 0.00	0.00, 0.00
	MEDIAN	1900.3	1813.9	1813.9	2.4	2.4	2.4
Overall*	MIN, MAX	822.6, 2977.9	1434.1, 5372.8	822.6, 5372.8	2.4, 2.4	2.4, 2.4	2.4, 2.4
	5%, 95%	822.6, 2977.9	1434.1, 5372.8	822.6, 5372.8	2.4, 2.4	2.4, 2.4	2.4, 2.4
	BLQ Values Included	0	0	0	3	2	5
	N	3	3	6	3	3	6
	MEAN, GEO MEAN	3783.1, 3152.8	3236.2, 3079.4	3509.7, 3115.9	3.7, 3.3	4.2, 3.6	4.0, 3.4
	SD, SE	2396.71, 1383.74	1296.85, 748.73	1749.33, 714.16	2.31, 1.33	3.18, 1.83	2.50, 1.02
Overall*	MEDIAN	3971.5	2695.3	3333.4	2.4	2.4	2.4
	MIN, MAX	1297.8, 6080.1	2297.3, 4715.9	1297.8, 6080.1	2.4, 6.4	2.4, 7.9	2.4, 7.9
	5%, 95%	1297.8, 6080.1	2297.3, 4715.9	1297.8, 6080.1	2.4, 6.4	2.4, 7.9	2.4, 7.9

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free 3-hydroxycotinine (nmol/L)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	4	8
	MEAN, GEO MEAN	16696.1, 14940.9	14366.9, 14092.1	15531.5, 14510.3	13.5, 10.3	12.2, 9.7	12.9, 10.0
	SD, SE	8158.34, 4710.22	3268.60, 1887.13	5703.03, 2328.25	12.46, 6.23	8.60, 4.30	9.94, 3.51
	MEDIAN	21097.5	16158.5	16253.2	8.3	11.2	8.3
	MIN, MAX	7282.3, 21708.6	10594.2, 16347.9	7282.3, 21708.6	5.7, 31.9	4.9, 21.6	4.9, 31.9
	5%, 95%	7282.3, 21708.6	10594.2, 16347.9	7282.3, 21708.6	5.7, 31.9	4.9, 21.6	4.9, 31.9
	BLQ Values Included	0	0	0	0	0	0
Week 2	N	3	3	6	3	4	7
	MEAN, GEO MEAN	17203.0, 13492.0	15228.1, 14505.1	16215.6, 13989.4	17.2, 14.6	9.4, 8.8	12.7, 10.9
	SD, SE	12805.30, 7393.14	5943.28, 3431.36	8993.85, 3671.72	10.55, 6.09	3.79, 1.90	7.86, 2.97
	MEDIAN	16061.2	13399.8	14730.5	17.4	8.6	10.3
	MIN, MAX	5006.9, 30541.0	10413.7, 21870.7	5006.9, 30541.0	6.5, 27.6	6.0, 14.3	6.0, 27.6
	5%, 95%	5006.9, 30541.0	10413.7, 21870.7	5006.9, 30541.0	6.5, 27.6	6.0, 14.3	6.0, 27.6
	BLQ Values Included	0	0	0	0	0	0
Week 3	N	2	3	5	2	3	5
	MEAN, GEO MEAN	8140.5, 7014.7	12045.1, 10508.6	10483.2, 8939.9	9.8, 9.4	12.3, 11.6	11.3, 10.7
	SD, SE	5841.55, 4130.60	7912.77, 4568.44	6664.13, 2980.29	3.89, 2.75	4.70, 2.71	4.09, 1.83
	MEDIAN	8140.5	8860.2	8860.2	9.8	12.4	12.4
	MIN, MAX	4009.9, 12271.1	6221.0, 21054.0	4009.9, 21054.0	7.0, 12.5	7.5, 16.9	7.0, 16.9
	5%, 95%	4009.9, 12271.1	6221.0, 21054.0	4009.9, 21054.0	7.0, 12.5	7.5, 16.9	7.0, 16.9
	BLQ Values Included	0	0	0	0	0	0
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	16011.5, 13273.5	13880.0, 13295.5	14945.7, 13284.5	11.9, 10.2	10.7, 9.8	11.3, 10.0
	SD, SE	10353.70, 5977.73	5163.80, 2981.32	7410.05, 3025.14	7.71, 3.85	4.99, 2.50	6.05, 2.14
	MEDIAN	16476.6	11810.8	14143.7	9.8	10.7	10.6
	MIN, MAX	5433.0, 26124.8	10071.7, 19757.5	5433.0, 26124.8	5.9, 22.2	5.5, 16.1	5.5, 22.2
	5%, 95%	5433.0, 26124.8	10071.7, 19757.5	5433.0, 26124.8	5.9, 22.2	5.5, 16.1	5.5, 22.2

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Free 3-hydroxycotinine (ng/mL)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	3	3	6	4	4	8
	MEAN, GEO MEAN	3209.0, 2871.7	2761.3, 2708.5	2985.2, 2788.9	2.6, 2.0	2.3, 1.8	2.5, 1.9
	SD, SE	1568.00, 905.29	628.25, 362.72	1096.11, 447.48	2.39, 1.19	1.69, 0.84	1.92, 0.68
	MEDIAN	4054.9	3105.7	3123.9	1.6	2.1	1.6
	MIN, MAX	1399.7, 4172.4	2036.2, 3142.1	1399.7, 4172.4	1.1, 6.1	0.9, 4.2	0.9, 6.1
	5%, 95%	1399.7, 4172.4	2036.2, 3142.1	1399.7, 4172.4	1.1, 6.1	0.9, 4.2	0.9, 6.1
	BLQ Values Included	0	0	0	0	0	0
Week 2	N	3	3	6	3	4	7
	MEAN, GEO MEAN	3306.4, 2593.2	2926.8, 2787.9	3116.6, 2688.7	3.3, 2.8	1.8, 1.7	2.4, 2.1
	SD, SE	2461.20, 1420.97	1142.28, 659.50	1728.63, 705.71	2.05, 1.18	0.70, 0.35	1.50, 0.57
	MEDIAN	3087.0	2575.4	2831.2	3.3	1.7	2.0
	MIN, MAX	962.3, 5870.0	2001.5, 4203.5	962.3, 5870.0	1.2, 5.3	1.2, 2.7	1.2, 5.3
	5%, 95%	962.3, 5870.0	2001.5, 4203.5	962.3, 5870.0	1.2, 5.3	1.2, 2.7	1.2, 5.3
	BLQ Values Included	0	0	0	0	0	0
Week 3	N	2	3	5	2	3	5
	MEAN, GEO MEAN	1564.6, 1348.2	2315.1, 2019.8	2014.9, 1718.2	1.9, 1.8	2.3, 2.2	2.1, 2.0
	SD, SE	1122.74, 793.90	1520.84, 878.06	1280.85, 572.81	0.78, 0.55	0.90, 0.52	0.79, 0.35
	MEDIAN	1564.6	1702.9	1702.9	1.9	2.4	2.4
	MIN, MAX	770.7, 2358.5	1195.7, 4046.6	770.7, 4046.6	1.3, 2.4	1.4, 3.2	1.3, 3.2
	5%, 95%	770.7, 2358.5	1195.7, 4046.6	770.7, 4046.6	1.3, 2.4	1.4, 3.2	1.3, 3.2
	BLQ Values Included	0	0	0	0	0	0
Overall*	N	3	3	6	4	4	8
	MEAN, GEO MEAN	3077.4, 2551.2	2667.7, 2555.4	2872.6, 2553.3	2.3, 1.9	2.1, 1.9	2.2, 1.9
	SD, SE	1990.01, 1148.93	992.49, 573.01	1424.22, 581.44	1.45, 0.73	0.95, 0.48	1.15, 0.40
	MEDIAN	3166.8	2270.0	2718.4	1.9	2.0	2.0
	MIN, MAX	1044.2, 5021.2	1935.8, 3797.4	1044.2, 5021.2	1.1, 4.2	1.1, 3.1	1.1, 4.2
	5%, 95%	1044.2, 5021.2	1935.8, 3797.4	1044.2, 5021.2	1.1, 4.2	1.1, 3.1	1.1, 4.2
	BLQ Values Included	0	0	0	0	0	0

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminating all BLQ values for the overall statistics.

TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Nicotine Glucuronide (nmol/L)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	31	49	28	35	63
	MEAN, GEO MEAN	3185.830, 1315.050	2857.660, 1385.610	2978.210, 1359.260	3.369, NA	0.511, NA	1.781, NA
	SD, SE	4046.8000, 953.8390	3716.0700, 667.4250	3802.1400, 543.1640	5.8234, 1.1005	1.5064, 0.2546	4.2499, 0.5354
	MEDIAN	1437.370	1405.000	1405.000	0.000	0.000	0.000
	MIN, MAX	17.879, 12968.078	59.184, 17624.502	17.879, 17624.502	0.000, 22.811	0.000, 6.782	0.000, 22.811
	5%, 95%	17.879, 12968.100	71.514, 10892.300	71.514, 11547.000	0.000, 18.495	0.000, 4.932	0.000, 9.248
	BLQ Values Included	0	0	0	18	34	52
Week 2	N	17	31	48	29	35	64
	MEAN, GEO MEAN	3220.380, 1984.940	3586.080, 1633.400	3456.560, 1750.150	5.166, NA	0.388, NA	2.553, NA
	SD, SE	3208.1800, 778.0980	4914.8800, 882.7380	4353.5900, 628.3870	18.3997, 3.4167	1.7119, 0.2894	12.5617, 1.5702
	MEDIAN	1499.950	1458.640	1479.290	0.000	0.000	0.000
	MIN, MAX	330.444, 10055.115	68.432, 25269.102	68.432, 25269.102	0.000, 99.257	0.000, 9.864	0.000, 99.257
	5%, 95%	330.444, 10055.100	106.038, 10255.500	121.451, 10055.100	0.000, 11.714	0.000, 2.466	0.000, 9.864
	BLQ Values Included	0	0	0	22	33	55
Week 3	N	16	29	45	30	36	66
	MEAN, GEO MEAN	2390.020, 1334.460	3029.460, 1504.190	2802.100, 1441.500	2.589, NA	0.240, NA	1.308, NA
	SD, SE	1832.9400, 458.2350	2699.1100, 501.2120	2424.2900, 361.3920	5.7411, 1.0482	0.8629, 0.1438	4.0615, 0.4999
	MEDIAN	2286.600	2594.230	2594.230	0.000	0.000	0.000
	MIN, MAX	27.126, 5382.662	12.330, 8494.754	12.330, 8494.754	0.000, 28.976	0.000, 4.316	0.000, 28.976
	5%, 95%	27.126, 5382.660	17.879, 8343.710	27.126, 8015.730	0.000, 11.714	0.000, 2.466	0.000, 6.165
	BLQ Values Included	0	0	0	23	35	58
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	2837.220, 1507.000	3047.120, 1633.130	2971.560, 1586.550	3.689, NA	0.383, NA	1.885, NA
	SD, SE	2855.8900, 673.1400	3367.0200, 595.2100	3164.2200, 447.4880	7.5385, 1.3763	1.1215, 0.1869	5.3651, 0.6604
	MEDIAN	1684.180	1332.880	1558.720	0.103	0.000	0.000
	MIN, MAX	22.503, 9135.910	68.432, 14522.700	22.503, 14522.700	0.000, 36.579	0.000, 5.549	0.000, 36.579
	5%, 95%	22.503, 9135.910	98.640, 11621.800	98.640, 9135.910	0.000, 19.112	0.000, 3.699	0.000, 7.707

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Nicotine Glucuronide (nmol/24hr)

Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	31	49	28	35	63
	MEAN, GEO MEAN	4026.810, 2152.390	4140.120, 2380.430	4098.500, 2293.980	5.227, NA	1.207, NA	2.994, NA
	SD, SE	3521.3800, 829.9970	4418.1200, 793.5190	4073.6500, 581.9500	8.9670, 1.6946	4.1795, 0.7065	6.9750, 0.8788
	MEDIAN	3048.350	2576.290	2740.960	0.000	0.000	0.000
	MIN, MAX	25.209, 10788.304	162.756, 22030.628	25.209, 22030.628	0.000, 29.594	0.000, 22.042	0.000, 29.594
	5%, 95%	25.209, 10788.300	185.043, 11202.800	162.756, 10788.300	0.000, 29.242	0.000, 11.235	0.000, 22.042
	BLQ Values Included	0	0	0	18	34	52
Week 2	N	17	31	48	29	35	64
	MEAN, GEO MEAN	4025.200, 2885.680	4619.800, 2660.690	4409.210, 2738.290	12.807, NA	0.814, NA	6.248, NA
	SD, SE	3025.1900, 733.7160	4867.0700, 874.1510	4279.9900, 617.7630	52.2807, 9.7083	3.7290, 0.6303	35.4753, 4.4344
	MEDIAN	3547.290	3511.090	3529.190	0.000	0.000	0.000
	MIN, MAX	461.543, 9872.580	177.318, 22489.501	177.318, 22489.501	0.000, 282.882	0.000, 21.701	0.000, 282.882
	5%, 95%	461.543, 9872.580	193.519, 16921.500	294.258, 11807.500	0.000, 23.674	0.000, 4.389	0.000, 14.886
	BLQ Values Included	0	0	0	22	33	55
Week 3	N	16	29	45	30	36	66
	MEAN, GEO MEAN	4351.610, 2285.070	4485.520, 2581.350	4437.910, 2471.850	4.535, NA	0.420, NA	2.290, NA
	SD, SE	3671.9000, 917.9750	3249.7700, 603.4680	3364.7100, 501.5820	8.5750, 1.5656	1.5602, 0.2600	6.1951, 0.7626
	MEDIAN	3945.800	4005.330	4005.330	0.000	0.000	0.000
	MIN, MAX	28.428, 11461.291	17.262, 12487.288	17.262, 12487.288	0.000, 37.669	0.000, 8.114	0.000, 37.669
	5%, 95%	28.428, 11461.300	52.296, 10420.500	52.296, 10485.800	0.000, 21.208	0.000, 4.279	0.000, 14.303
	BLQ Values Included	0	0	0	23	35	58
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	3965.130, 2293.940	4289.750, 2765.080	4172.890, 2585.250	7.466, NA	0.815, NA	3.838, NA
	SD, SE	3288.3000, 775.0590	3668.2900, 648.4680	3505.6200, 495.7700	19.3413, 3.5312	2.5735, 0.4289	13.4760, 1.6588
	MEDIAN	3242.430	2982.790	3084.910	0.137	0.000	0.000
	MIN, MAX	26.819, 10353.300	133.990, 15441.800	26.819, 15441.800	0.000, 104.041	0.000, 11.885	0.000, 104.041
	5%, 95%	26.819, 10353.300	199.791, 12852.600	199.791, 11219.200	0.000, 21.634	0.000, 10.052	0.000, 18.618

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Nicotine Glucuronide (nmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	31	49	28	35	63
	MEAN, GEO MEAN	2.667, 1.629	3.223, 2.054	3.019, 1.886	0.003, NA	0.001, NA	0.002, NA
	SD, SE	1.8782, 0.4427	2.6290, 0.4722	2.3754, 0.3393	0.0061, 0.0012	0.0031, 0.0005	0.0047, 0.0006
	MEDIAN	2.644	3.131	2.774	0.000	0.000	0.000
	MIN, MAX	0.024, 7.058	0.135, 12.113	0.024, 12.113	0.000, 0.023	0.000, 0.016	0.000, 0.023
	5%, 95%	0.024, 7.058	0.187, 7.068	0.135, 7.058	0.000, 0.021	0.000, 0.008	0.000, 0.012
	BLQ Values Included	0	0	0	18	34	52
Week 2	N	17	31	48	29	35	64
	MEAN, GEO MEAN	2.720, 2.069	3.522, 2.113	3.238, 2.097	0.011, NA	0.001, NA	0.005, NA
	SD, SE	1.8726, 0.4542	3.6051, 0.6475	3.1048, 0.4481	0.0499, 0.0093	0.0028, 0.0005	0.0338, 0.0042
	MEDIAN	2.323	2.864	2.471	0.000	0.000	0.000
	MIN, MAX	0.298, 6.734	0.153, 17.646	0.153, 17.646	0.000, 0.270	0.000, 0.016	0.000, 0.270
	5%, 95%	0.298, 6.734	0.193, 11.734	0.222, 6.805	0.000, 0.017	0.000, 0.004	0.000, 0.011
	BLQ Values Included	0	0	0	22	33	55
Week 3	N	16	29	45	30	36	66
	MEAN, GEO MEAN	2.776, 1.558	3.701, 2.200	3.372, 1.946	0.002, NA	0.001, NA	0.001, NA
	SD, SE	2.1773, 0.5443	2.7698, 0.5143	2.5882, 0.3858	0.0045, 0.0008	0.0017, 0.0003	0.0034, 0.0004
	MEDIAN	2.549	3.179	2.840	0.000	0.000	0.000
	MIN, MAX	0.025, 6.372	0.020, 10.645	0.020, 10.645	0.000, 0.021	0.000, 0.008	0.000, 0.021
	5%, 95%	0.025, 6.372	0.056, 9.700	0.056, 8.031	0.000, 0.011	0.000, 0.006	0.000, 0.008
	BLQ Values Included	0	0	0	23	35	58
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	2.612, 1.659	3.483, 2.345	3.169, 2.071	0.006, NA	0.001, NA	0.003, NA
	SD, SE	1.9175, 0.4520	2.6610, 0.4704	2.4360, 0.3445	0.0177, 0.0032	0.0020, 0.0003	0.0121, 0.0015
	MEDIAN	2.521	2.952	2.648	0.000	0.000	0.000
	MIN, MAX	0.025, 6.721	0.120, 10.339	0.025, 10.339	0.000, 0.097	0.000, 0.009	0.000, 0.097
	5%, 95%	0.025, 6.721	0.190, 9.409	0.190, 8.383	0.000, 0.013	0.000, 0.008	0.000, 0.009
	BLQ Values Included	0	0	0	23	35	58

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Cotinine Glucuronide (nmol/L)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	12775.700, 5928.170	11946.900, 6284.200	12245.200, 6153.630	12.447, NA	3.515, NA	7.575, NA
	SD, SE	15906.0000, 3749.0900	12768.6000, 2257.1900	13823.3000, 1954.9100	24.9161, 4.5490	7.4771, 1.2462	18.0877, 2.2264
	MEDIAN	6149.150	6802.620	6149.150	2.554	0.000	0.000
	MIN, MAX	71.505, 58435.475	103.285, 57183.003	71.505, 58435.475	0.000, 121.445	0.000, 31.780	0.000, 121.445
	5%, 95%	71.505, 58435.500	193.518, 41739.100	193.518, 44549.900	0.000, 49.373	0.000, 23.268	0.000, 38.023
	BLQ Values Included	0	0	0	19	31	50
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	12429.200, 6666.940	15118.100, 8074.150	14130.400, 7525.660	14.169, NA	4.114, NA	8.685, NA
	SD, SE	14018.0000, 3304.0700	16526.1000, 2968.1700	15556.5000, 2222.3600	24.9605, 4.5571	7.0808, 1.1801	18.1773, 2.2375
	MEDIAN	8346.790	6741.330	7567.610	2.554	0.000	0.568
	MIN, MAX	73.775, 60546.008	286.588, 77152.193	73.775, 77152.193	0.000, 92.503	0.000, 24.970	0.000, 92.503
	5%, 95%	73.775, 60546.000	310.423, 42264.000	310.423, 42264.000	0.000, 71.505	0.000, 20.430	0.000, 57.318
	BLQ Values Included	0	0	0	18	30	48
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	9575.360, 5758.280	12155.200, 7318.110	11201.800, 6697.690	8.929, NA	2.585, NA	5.469, NA
	SD, SE	7119.6800, 1726.7800	10191.7000, 1892.5500	9178.1500, 1353.2400	16.0375, 2.9280	6.4599, 1.0766	12.1389, 1.4942
	MEDIAN	8817.820	8595.360	8706.590	1.987	0.000	0.000
	MIN, MAX	81.153, 23770.305	160.035, 37456.135	81.153, 37456.135	0.000, 78.883	0.000, 28.943	0.000, 78.883
	5%, 95%	81.153, 23770.300	900.623, 29846.500	756.478, 27258.700	0.000, 36.320	0.000, 19.863	0.000, 22.700
	BLQ Values Included	0	0	0	18	33	51
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	11720.700, 6790.710	12733.500, 7363.960	12368.900, 7152.220	11.848, NA	3.405, NA	7.243, NA
	SD, SE	10966.1000, 2584.7400	12218.3000, 2159.9100	11679.4000, 1651.7200	18.0395, 3.2936	6.1136, 1.0189	13.5374, 1.6663
	MEDIAN	9090.310	7428.200	8028.620	4.351	0.284	0.852
	MIN, MAX	75.478, 44996.300	221.325, 53864.600	75.478, 53864.600	0.000, 74.910	0.000, 23.268	0.000, 74.910
	5%, 95%	75.478, 44996.300	430.165, 31626.000	430.165, 31626.000	0.000, 52.400	0.000, 23.079	0.000, 33.293

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
(Page 104 of 7)

Biomarker: Cotinine Glucuronide (nmol/24hr)		Smokers			Non-Smokers		
Timepoint	Statistic	Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	17099.600, 9702.850	17856.800, 11002.500	17584.200, 10515.700	18.077, NA	7.013, NA	12.042, NA
	SD, SE	16437.9000, 3874.4400	14914.9000, 2636.6100	15317.2000, 2166.1700	31.1255, 5.6827	17.6358, 2.9393	25.1101, 3.0908
	MEDIAN	14284.800	13051.200	13520.000	2.645	0.000	0.000
	MIN, MAX	100.822, 68661.683	284.034, 60518.854	100.822, 68661.683	0.000, 106.872	0.000, 75.621	0.000, 106.872
	5%, 95%	100.822, 68661.700	561.202, 52173.800	561.202, 52173.800	0.000, 106.084	0.000, 72.395	0.000, 75.621
	BLQ Values Included	0	0	0	19	31	50
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	15578.800, 9437.530	19694.100, 13152.200	18182.400, 11642.600	23.010, NA	8.530, NA	15.112, NA
	SD, SE	12680.2000, 2988.7600	15548.2000, 2792.5400	14562.1000, 2080.3000	43.7941, 7.9957	15.2176, 2.5363	32.1430, 3.9565
	MEDIAN	14129.700	14973.800	14973.800	2.566	0.000	0.698
	MIN, MAX	66.398, 54491.407	453.218, 68665.452	66.398, 68665.452	0.000, 203.789	0.000, 54.934	0.000, 203.789
	5%, 95%	66.398, 54491.400	523.023, 55852.000	523.023, 54491.400	0.000, 103.001	0.000, 44.129	0.000, 73.080
	BLQ Values Included	0	0	0	18	30	48
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	17262.700, 9735.880	18129.700, 12558.600	17809.300, 11430.900	15.560, NA	5.004, NA	9.802, NA
	SD, SE	13557.2000, 3288.1100	11936.9000, 2216.6400	12417.3000, 1830.8400	27.1386, 4.9548	12.8637, 2.1440	21.1127, 2.5988
	MEDIAN	14321.900	17401.000	16848.200	3.388	0.000	0.000
	MIN, MAX	85.048, 48342.568	224.049, 48692.976	85.048, 48692.976	0.000, 105.328	0.000, 52.637	0.000, 105.328
	5%, 95%	85.048, 48342.600	1675.160, 37176.400	1043.940, 37176.400	0.000, 102.548	0.000, 50.216	0.000, 50.216
	BLQ Values Included	0	0	0	18	33	51
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	16709.600, 10031.400	18082.400, 12337.100	17588.200, 11451.600	18.882, NA	6.849, NA	12.319, NA
	SD, SE	13467.5000, 3174.3200	13234.3000, 2339.5100	13197.5000, 1866.4100	29.3085, 5.3510	12.9985, 2.1664	22.5981, 2.7816
	MEDIAN	16733.600	15450.600	15932.300	4.780	0.250	1.638
	MIN, MAX	84.089, 57165.200	412.823, 46589.500	84.089, 57165.200	0.000, 104.966	0.000, 48.839	0.000, 104.966
	5%, 95%	84.089, 57165.200	827.405, 46579.300	827.405, 46579.300	0.000, 97.288	0.000, 42.815	0.000, 50.161

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TABLE 14.4-2
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER
OF 24-HOUR URINE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL
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Biomarker: Cotinine Glucuronide (nmol/mg Creatin)							
Timepoint	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
Week 1	N	18	32	50	30	36	66
	MEAN, GEO MEAN	11.128, 7.340	14.577, 9.595	13.335, 8.713	0.011, NA	0.006, NA	0.008, NA
	SD, SE	7.4252, 1.7501	10.3373, 1.8274	9.4621, 1.3381	0.0210, 0.0038	0.0134, 0.0022	0.0173, 0.0021
	MEDIAN	10.682	14.598	12.095	0.002	0.000	0.000
	MIN, MAX	0.095, 27.231	0.236, 37.108	0.095, 37.108	0.000, 0.075	0.000, 0.055	0.000, 0.075
	5%, 95%	0.095, 27.231	0.507, 36.704	0.507, 33.762	0.000, 0.066	0.000, 0.049	0.000, 0.055
	BLQ Values Included	0	0	0	19	31	50
Week 2	N	18	31	49	30	36	66
	MEAN, GEO MEAN	10.408, 6.935	15.196, 10.444	13.437, 8.986	0.016, NA	0.007, NA	0.011, NA
	SD, SE	6.8410, 1.6124	11.8468, 2.1277	10.4751, 1.4964	0.0371, 0.0068	0.0121, 0.0020	0.0267, 0.0033
	MEDIAN	10.268	13.259	11.760	0.002	0.000	0.001
	MIN, MAX	0.074, 26.176	0.392, 53.877	0.074, 53.877	0.000, 0.195	0.000, 0.045	0.000, 0.195
	5%, 95%	0.074, 26.176	0.522, 38.730	0.522, 34.914	0.000, 0.058	0.000, 0.039	0.000, 0.043
	BLQ Values Included	0	0	0	18	30	48
Week 3	N	17	29	46	30	36	66
	MEAN, GEO MEAN	11.268, 7.027	15.296, 10.711	13.808, 9.166	0.008, NA	0.005, NA	0.006, NA
	SD, SE	7.7146, 1.8711	11.2894, 2.0964	10.2141, 1.5060	0.0151, 0.0028	0.0136, 0.0023	0.0143, 0.0018
	MEDIAN	9.472	14.211	14.106	0.002	0.000	0.000
	MIN, MAX	0.075, 22.527	0.264, 49.743	0.075, 49.743	0.000, 0.060	0.000, 0.067	0.000, 0.067
	5%, 95%	0.075, 22.527	1.668, 40.962	1.668, 34.847	0.000, 0.057	0.000, 0.035	0.000, 0.035
	BLQ Values Included	0	0	0	18	33	51
Overall*	N	18	32	50	30	36	66
	MEAN, GEO MEAN	10.959, 7.253	14.900, 10.481	13.481, 9.180	0.012, NA	0.006, NA	0.008, NA
	SD, SE	7.0907, 1.6713	10.5712, 1.8687	9.5809, 1.3549	0.0208, 0.0038	0.0118, 0.0020	0.0165, 0.0020
	MEDIAN	11.094	14.601	12.611	0.002	0.000	0.001
	MIN, MAX	0.081, 23.794	0.388, 38.906	0.081, 38.906	0.000, 0.091	0.000, 0.049	0.000, 0.091
	5%, 95%	0.081, 23.794	0.809, 38.799	0.809, 38.061	0.000, 0.061	0.000, 0.038	0.000, 0.047
	BLQ Values Included	0	0	0	18	33	51

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